PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

Monday,
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Renaissance Denver Hotel
3801 Quebec Street
Denver, Colorado

[FROM WEBCAST]

B&B REPORTERS
701 Copley Lane
Silver Spring, MD 20904
[301] 384-2005

APPEARANCES:

BOARD OF GOVERNORS

Debra Barksdale, PhD, RN
Kerry Barnett, JD
Lawrence Becker
Carolyn Clancy, MD
Leah Hole-Curry, JD
Allen Douma, MD
Arnold Epstein, MD
Christine Goertz, DC, PhD
Gail Hunt
Robert Jesse, MD, PhD
Richard E. Kuntz, MD, MSc
Sharon Levine, MD
Freda Lewis-Hall, MD
Steven Lipstein, MHA (Vice Chair)
Grayson Norquist, MD, MSPH
Ellen Sigal, PhD
Eugene Washington, MD, MSc (Chair)
Harlan Weisman, MD
Robert Zwolak, MD, PhD

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P R O C E E D I N G S

[8:34 AM]

CHAIRMAN WASHINGTON: We're live. Good morning, everyone, particularly to board members. It's great to see you. As all of you know, we have an extremely busy agenda today, and by the end of the day, I believe we will have significantly advanced the mission of PCORI. I want to welcome all of those of you who've joined us here in person in Denver, as well as those of you who are joining us via webcast. This is a public meeting and if you have friends or colleagues who don't know about it and would like to join us, you can find instructions on the PCORI website at www.PCORI.org under Events. You can also signup for the public comment period and if you have questions at any point during the day, you can e-mail them to us at info@PCORI.org. This is our tenth meeting of the Board, dating back to our first meeting in November of 2010.

So, I think it's fitting that approximately 20 months later, we're at a point

where we'll well-organized and have gained momentum and we're funding research that we think will change the landscape as it relates to health and health care in America, particularly from the perspective of patients, the caregivers, and our other stakeholders.

And so, with that introduction, I would like to first ask board members if you have any comments on the minutes and I want to have a motion to approve the two different sets of minutes. So, I'll start with first --

DR. SELBY: We're going to postpone the Jacksonville minutes just for a little while. So, we'll just do the Baltimore minutes right now.

CHAIRMAN WASHINGTON: Okay, great.

Okay, we're going to comment and vote on the Baltimore minutes, which are the minutes from our last meeting, which would have been in March.

Is there a motion?

UNIDENTIFIED BOARD MEMBER: So moved.

CHAIRMAN WASHINGTON: So moved. Is there a motion?

UNIDENTIFIED BOARD MEMBER: Second.

CHAIRMAN WASHINGTON: Second. Comments? Corrections, concerns? All in favor?

[Chorus of ayes.]

CHAIRMAN WASHINGTON: All opposed?

[No response.]

CHAIRMAN WASHINGTON: Okay, so, the motion carries and the minutes from our last board meeting in Baltimore are approved.

And with that, I'm going to turn the meeting over to our Executive Director, Dr. Joe Selby.

DR. SELBY: Thank you, Gene. Good morning, everybody.

CHAIRMAN WASHINGTON: Good morning.

UNIDENTIFIED BOARD MEMBER: Good morning.

DR. SELBY: We left Baltimore ten weeks ago and we had a very busy, very full plate, all of us did, whether we were the Board, the Methodology Committee, or the staff, and now we're at a point which really does feel like a milestone in many ways, several. We're going to hopefully wrap-up

several of our statutory obligations at this meeting. We wouldn't be doing this without the ongoing, amazing participation of the Board members, and so, particularly on behalf of the staff, we would like to say thank you to the Board members, and I'll enumerate some of the ways that you've been helpful over the last two-and-a-half months in just a minute.

We certainly wouldn't be where we are without the Methodology Committee, and we will hear from Sherine shortly, who for the last 15 months, have been just risking their jobs almost, the amount of time they've put into building a methodology report, which we've had the pleasure now of seeing for the last ten days. It was delivered May 10th to the Board. We'll hear a report on that and plans for public comment, but that's very exciting. And we would not be here today and where we are if it weren't for the remarkable efforts of a growing staff. So, I want to also, and I wasn't always able to do this, but to commend an amazing staff, which is up to 20 now

and I think impresses each other from day to day with their ability to go above and beyond. So, thank you.

So, if we have accomplished some of our statutory requirements, then perhaps we are now at the point where we can be PCORI and that's what it feels that we're doing today. We're starting to -- and maybe they'll make a movie someday "Being PCORI."

[Laughter.]

DR. SELBY: But it feels very exciting.

This is a diagram from our research agenda, our National Priorities in Research Agenda Document. We have a virtuous cycle over time in which with the collaboration of patients and stakeholders, our priorities, and our research agenda are formulated. That leads to preparations of funding announcements and funding research. That leads in turn to results and dissemination, which we share with patients and stakeholders, and that helps us then in turn refine the priorities.

And, today, we're going to hopefully

finalize the first version of our priorities in our research agenda. We're going to announce some research that has been funded and large funding announcements that follow on a formation of the research agenda. We're not quite yet at the point of disseminating results, but we've taken the steps that are going to get us there.

And, today, as I said, we put the priorities in the research agenda together in consultation with a wide range of stakeholders. So, we've had a lot of opportunities to get stakeholder input. What we can do now as we're being PCORI is formalize those relationships and make them permanent. Let the world know, let patients and our other stakeholder partners know how to engage with us over time, make certain that it's a two-way engagement, and we're going to hear about that today.

So, this is just a preview of today's agenda. I'm going to say just a bit about our move and celebrate that. I want to say a bit more about the PCORI Pilot Projects because they are funded

and that's a point of celebration. Then we will hear from Sherine and she will deliver the Methodology Report to us, we'll have some discussion, and we'll hear a plan for how we get public comment on the Methodology Report. You recall that the Methodology Report is one of the products that we statutorily must get public comment on and we have a plan for doing that. You will then hear about a preliminary, strategic plan that the Board has been deliberating on and we'll discuss it today.

Next is the proposed final version of the National Priorities in Research Agenda and you will hear about that from Leah Hole-Curry. We've taken public comment, we've revised the agenda, the priorities in the agenda, and you'll hear about those revisions and hopefully, the Board will vote to adopt the priorities and agenda at today's meeting.

Then you will hear about funding announcements. So, we have approximately $96 million worth of funding announcements or up to

that amount that will be released shortly after we present it today. And then we begin talking about the future or where we go from here and you will hear from PCORI's Engagement Team, our engagement personnel on plans for establishing, as I said, the formal links between patients and stakeholders and PCORI so that we can launch and continue the process of generating research ideas, identifying the ideas that are most crucial to patients and the stakeholders, prioritizing them and getting on with funding.

You will hear the results of the first PCORI audit, and last today, we will have an important discussion about a proposed policy on conflict of interest from PCORI's Standing Committee on conflict of interest from Larry Becker. So, that's today.

So, the move happened. We hardly noticed it. I know that some staff members worked late into the evenings and weekends and over a weekend. Those of us who were writing the PFAs or doing the other work hardly noticed it. We came to work one

day at 1701 Pennsylvania and we came to work the next day here at 1828 L Street and hardly missed a beat. It has just turned into a lovely space. Thanks to Anne, Mark, and others, the place looks beautiful, it's not extravagant, but it's extraordinarily comfortable, light, and airy, feels very modern and just a pleasure to be in the space. It's 13,000 square feet. It's located very close to both the Red, Blue, and what is it Yellow lines or --

UNIDENTIFIED SPEAKER: Orange. Blue and Orange.

DR. SELBY: Blue and Orange Lines. I never take the Orange. And it's an extraordinarily green building. We have a great landlord. So, I want to just remind you that we are going to have an open house on the evening of June 13, which everybody in this room is invited. Please let us know, invites will go out later this week, but we hope that at least those of you who are in the vicinity can join us and see our space. Some of you I know already have seen it.

I want to also celebrate the arrival of our newest PCORI scientist. This is Rachael Fleurence, and without Rachael, we wouldn't have the PFAs to discuss with you today. She just came in and hit the ground running and a pleasure to work with Rachael. Rachael was trained at the University of York, where she has a Master's and a Ph.D. The Ph.D. is in Health Sciences and her expertise is value of information, indirect comparisons of outcomes, and health economics. So, she will be very involved in our ongoing discussions about, among other things, research prioritization.

And now I want to celebrate just for a minute because if we weren't so busy with other items, we'd take even more time, but I want you all and the world to know that we have funded approximately $31 million in pilot projects. Fifty projects have been approved. The awardees will be posted on the PCORI website within the week. You'll recall that this research was not CER, was not patient-centered outcomes research, comparative

research, per se, by statute. We had to wait for the research agenda to be finalized and adopted before we could fund that kind of research. So, this is methodologic research on ways to engage patients in various aspects of the research process, and I'll show you in a minute what those are.

So, these are the eight areas of interest and they are all about engaging patients and stakeholders in some aspect of research. So, we have three projects that are dedicated to informing PCORI's national priorities, so, engaging patients and stakeholders in informing priorities. Two projects in engaging patients and stakeholders in the entire research process. A very large number of projects, 19 projects on aspects of engaging patients in building decision support tools that account for patient preferences.

So, you have everything from autism to preferences regarding chronic pain to decisions about transferring patients from a nursing home to a hospital. A wide range and I think we'll learn a

lot if we keep a close eye on these 19 projects on decision aids.

There were no projects submitted that scored well in the area of identifying gaps in comparative effectiveness knowledge, and this isn't too surprising to me. It's not real different from informing priorities and prioritizing, but I think it's just the case that probably there has not been thinking or work yet about engaging patients as stakeholders in that process. We may, therefore -- - first of all, we'll consult with the various background papers prepared by the Methodology Committee and hand in hand with the Methodology Committee, we'll ask ourselves whether we actually need to commission some kind of research in this area.

There were 12 projects developing patient-centered outcomes instruments. So, again, a wide range of conditions. There were four on engaging patients and other stakeholders in researching behaviors, lifestyles, and choices that patients make, six on studying the patient care team

interactions on the patient care team in situations where multiple options are being deliberated, and there were seven that were dedicated to analytic methods of comparative effectiveness or patient-centered outcomes research. So, that is our initial portfolio.

We reviewed the 50 to make sure that they included diverse patient populations and they did pediatric topics, 4 dedicated to aging, 2 consider populations of patients who are disabled, and 9, consider specific racial ethnic groups. You also see here that a number of different conditions are represented by one or more populations and a number of them are not dedicated to a particular condition so they were crosscutting pieces of research. And it's pretty good considering that there were 50; there's fairly good representation across the states and across every sector of the country. So, 24 states and the District of Columbia received at least 1 pilot project award.

This can't be closed out, this discussion, without several thank yous. So, the first thank

yous go to Christine Goertz and Gail Hunt, who really were the Board members -- they frankly wrote the PFA. This was put together largely before I arrived, before any staff arrived. They were supervising consultants themselves and they were really doing most of the work themselves.

Then there was a Selection Committee chaired by Gray Norquist with these board members who did a really wonderful job of creating a set of criteria that we wanted to make sure that the projects were balanced on and then making a decision about keeping in mind primarily the priority scores from the study section review, but also keeping in mind factors that we wanted to balance on. And the good news was that the 50 were really quite balanced, as I showed you, without having to make any particular other decisions.

Yes, Harlan?

DR. WEISMAN: Harlan Weisman, Member of the Board.

Joe, it's really nice to see the culmination of all the hard work that went into

this over many months and we now have funded grants. Because it's been many months and a lot of things have happened, could you remind me and perhaps the public and other board members when these are completed and now that they're underway, we will get results from them, how we intend to use the outcomes of these studies and the work of PCORI and how does it interweave with the work, say, of the Methodology Committee and their report, which we're going to hear more about this morning. I mean, I know it's a ways off, but at some point, and maybe we already have those plans laid out and I just don't remember it.

DR. SELBY: Thanks. Well, we call these Pilot Projects, and they were Pilot Projects in a number of ways. So, now that we have this bolus of work pretty much wrapped up that I've mentioned, one of the things we're anxious to get back to is looking at the Pilot Projects because we think there's information we can learn just from looking at what was submitted and there's definitely information we can learn from the review process.

So, one of the things we want to do is look -- if you recall, there were 850 applications and we want to look at the range how those 850 divided themselves for, among other things, geographically, but also by area of interest. We want to look at the data from the reviews in terms of how much the patient engagement score drove the total scores. We have preliminary evidence that it had a big effect, but we want to make sure that patient engagement, the criterion that we added to the review actually has a substantial impact on driving the final scores and, therefore, funding. That's one thing.

We also want to see how the reviewers assessed the presence of the patient and stakeholder engagements, reviewers on the team. So, if you recall, we had three patient and stakeholder reviewers on each team, and we interviewed both the patient and stakeholders and the technical reviewers and we're very anxious to get to what they said about the interactions and whether it went well or not.

And the last thing is, and we began talking about this at the PDC last night, how do we learn from these as we go through them, even before the end? We really think that we will get information. For example, in many cases, they'll be two, three, or four projects that have a connection. You saw the 19 on decision aids. We hope that we'll be able to sort of get information as we move along and share information between projects on what's important from the patients' perspective and putting these decision aids together. We talked about this at the Program Development Committee last night and we also talked about taking some of this information back to stakeholders in an ongoing way.

Christine?

DR. GOERTZ: Just one thing to add. We also asked all the investigators to write into their budget funds to attend a PCORI meeting about a year from when they got funded so that we could pull people together and get an update on where they're at and, again, use this information as we

continue to evolve our research agenda and our priorities.

DR. WEISMAN: Thank you. Those really were very helpful comments. Because we are learning. I mean, together with investigators and others, going down new territory and creating the trail. As we learn, as the PDC learns, as the institute learns, as individuals, and the public and scientists and others will learn along with this, I was really wondering about do we have plans for how we share our learnings as we go so that the greater community is learning along with us?

DR. SELBY: Well, as I said, one of the ways we want to do this is by gathering the researchers. The second is by reporting it back to stakeholders in various venues as we convene these groups. So, I think those are the two ways that we could do it before the research is finished. Yes.

Sherine?

DR. GABRIEL: Thank you. Sherine Gabriel, Chair of the Methodology Committee.

I had a comment related to the

intersection between what's going on with studying, what we learned from the Pilot Projects and the Methodology Committee. So, last night also at the PDC, Rachael Fleurence, the new staff member that you were all introduced to, talked about her plans to take some of the learnings and some of the work that the Methodology Committee has put together regarding value of information, research prioritization, peer review, and really use those approaches to try and understand not only the pilot grants, but grants going forward, of course with the direction of the PDC and with input from the Methodology Committee. So, it's really a nice intersection of how we use some of the things we've learned in the Methodology Committee and through the Methodology Report and then apply them to the work of PCORI.

DR. WEISMAN: You know, I was sort of -- you know how IOM have either ongoing working groups or have commissioned something, they publish a book afterwards, a proceedings or something that is each comprising articles by the various groups and so

forth and I was wondering whether we're contemplating something like that that is a --

DR. SELBY: We are now.

DR. WEISMAN: Somebody can go look.

DR. SELBY: We will now. Let's see, a couple more quick comments and then we should finish this up and get onto the Methodology Report. Bob and then Gail.

DR. ZWOLAK: Bob Zwolak, Board Member.

Are these mostly two-year grants or --

DR. SELBY: Almost all two-year grants, Bob.

DR. ZWOLAK: -- realistically, the hard results we'll be looking at will be available sort of end of 2014?

DR. SELBY: The hard results, but, again, to Harlan's point; I think we really would like to see if we can't get some learnings out of them sooner.

Gail?

MS. HUNT: Gail. Small point, but I was on the Selection Committee.

DR. SELBY: Oh, that's right. Double thank you. That's a big point.

Okay, in the spirit of celebration.

[Applause.]

DR. SELBY: A mole back at Kaiser Permanente shot me this last week, our own Sharon Levine received two awards right on the heels of each other. The first, she was named Woman of the Year by Women Health Care Executives, a San Francisco Bay Area organization, and just after that, she received the Industry Leader Award from the Professional Business Women of California, an organization promoting development of women and as leading business professionals in California and nationwide. So, Sharon, not surprised, but congratulations.

[Applause.]

DR. SELBY: And I was also sent a lot of the comments she made in response, which was largely how exciting her work has been over the years and what a pleasure it has been, she said, working in a Permanente Medical Group, which I can

resonate with.

Okay, I want to also point out to everyone that there is a subtle, but meaningful, transition in the Board meeting agenda format this time. So, if you recall that up to this point, we've always heard one-by-one from the committees. Now that there is staff and now, as you will hear a little bit later, there is a strategic plan with a number of imperatives, the agenda will be organized by imperatives instead of by committees, and oftentimes, they'll be a committee behind the work, sometimes, there may be two committees behind the work or all three. But this will represent work typically led by staff and with the advice and consultation of committees. So, one is on our research itself, funding and conducting the research.

One is one engagement of patients and our other stakeholders. The third is on developing and disseminating rigorous research methods. The fourth is one building an infrastructure for conducting patient-centered outcomes research. The

fifth is on disseminating research findings. And the sixth is on efficient and transparent operations. So, that's the way by and large that we will bring topics to the Board going forward.

DR. DOUMA: Joe?

DR. SELBY: Yes, Allen.

DR. DOUMA: Yes, I just want to comment I think it's important we don't lose track of the fact that this is a board meeting, it's not necessarily a PCORI staff board meeting, and the Board has certain fiduciary responsibilities having to do with governance and audit and finance that are different than the strategic plan that we're talking about here and we need to have that as integral to our agenda, as well as running a board itself is a job and we need to not forget that we have to have on our agenda discussions about how we work as a board, how efficient are we as a board? So, I think it's important not to turn this meeting into a wonderful way to discuss what PCORI is doing and get too far away from what a board should be doing.

Strategic Plan

DR. SELBY: Thanks.

CHAIRMAN WASHINGTON: I would say, Allen, I agree with you completely and I pay attention to that as we are planning the agenda and on the former part of your statements, you will notice when you get down we have two sections in which we talk about financing administration, which we deal with, those business-related issues, but in terms of our own performance, you raise an important point that we need to ensure that we are discussing that in public, as well. Okay.

DR. SELBY: So, on that, Gene --

CHAIRMAN WASHINGTON: Yes.

DR. SELBY: If there are no more questions, I'll turn it back to you.

CHAIRMAN WASHINGTON: Okay, and thanks, Joe. So, as all of you can see, board members and staff, as well as those who are participating, representing the public, we have been busy and I'd like to think we've been productive. Certainly one of the thickest documents that's coming out of

PCORI today is the report from the Methodology Committee. And while Joe highlighted that board members have been involved in all of these activities, I would just also like to note that for each one of these major reports today, we asked selected board members to sort of serve as point people and to go deeper while all the Board members were asked to review documents, and in this case, in reviewing the Methodology Committee Report, many board members provided comments, but upfront, we asked Harlan K., who's not here, and Arnie, who is here, and Debra and Bob Z. to pay particular attention and I will point out who paid particular attention when we discuss some of the other reports.

So, I want to convey a hearty thanks to those board members and particularly to all the Board members who provided comments.

And, with that, I am going to turn this over to Dr. Sherine Gabriel, who's chair of the Methodology Committee. And give us a little context --

DR. GABRIEL: Okay.

CHAIRMAN WASHINGTON: Which I'm sure you will.

DR. GABRIEL: I will do, and I actually have that as part of my slide. So, thanks very much. It's really my pleasure today to present to you an overview of the first Methodology Report that we presented to the Board as directed by staff on May 10th with, I don't know, something like 13 minutes to spare. So, Harlan isn't here, but I thought of opening my talk today with really a couple of quotes from board members that reflect some of the motivation for the Methodology Report and the methodologic standards, and as many of you recall, Harlan's impassioned talks at the National Patient and Stakeholder Dialogue, where he said "this is going to be research differently."

And so, we believe that some of the methodologic standards and some of the discussions in the Methodology Report really speak directly to this, done different how, and this is what we are trying to address. And I'm also quoting Larry

Becker, who has more than once said "The Methodology Committee is writing the source code." So, along the same lines that we really are the how-to committee and we're moving down that path.

So, in terms of the agenda for today, and I'm going to be tag-teaming a little bit here with Bill, who'll come up shortly. There you are. So, I'm going to give you a little bit of a background on I think it's what most of you here know, but, perhaps, some in the public may not know, background of why we're doing the Methodology Report, what is it that the statute really directs us to do and directed us to do, an overview of the steps we took to accomplish it, and then Bill's going to help me by discussing the process for the public comment period, the communications plan, we're going to put this out in the public and what kinds of tools we're planning to build in order to capture public comment and use that to help us improve the report going forward.

Our requests to you are really at this early stage as we put the initial report out for

review and consideration by potential applicants that that will be done by June 4th, just within a few days, and then as we consider the public comment period, that you'll hear about from Bill, look at the plan we're presenting and we're really looking for a discussion around that.

And then, finally, I'm going to give you a sense of what we're thinking about in terms of what's next for the Methodology Committee and then I've had with Dr. Washington's permission and the good Joe Selby's approval, I've got a little surprise at the very end, just a three-minute surprise. So, I hope that'll keep everyone kind of awake and interested for the rest of the --

[Laughter.]

DR. NORQUIST: It better be good.

DR. GABRIEL: It better be good. Well, gee.

UNIDENTIFIED BOARD MEMBER: Will we know when it starts?

DR. GABRIEL: You will know when it starts, and I'll say a little bit more about that

at the end.

So, in terms of setting the stage, as Gene said, really wheat I will do in the next few minutes is share with you the steps that we have taken to deliver this report to the Board. While we --

[Webcast stopped for 22 minutes.]

DR. GABRIEL: [Continuing] -- really help us bring this forward and then in interim, PCORI researcher in partnership with Steve Goodman, who chairs the Research Methods Group and with input from the broader PC conducted a review on reproducible and transparent research and that's eluded to a little bit in the report, but really the main goal of that was to understand what's known, again best practices, around methods surrounding reproducible research and data sharing policies and use that working with the staff to help inform PCORI policies on those items.

So, the 17 reports address the 15 topics that I'll just list very briefly here. All of those reports are part of the Methodology Report,

and I think they've been posted for a few days now, and so, anybody who's interested, they're actually very well-done reports, we think, and have a lot of information that's relevant to our work and these are the broad topics that they address: patient-reported outcomes measures, registries, missing data, distributed data networks, diagnostic testing, causal inference methods from observational and experimental studies, heterogeneity, which we talk about a good deal, involving patients in topic generation, kind of eluding to a question that Harlan W. asked this morning, value of information, peer review, examining research gaps, how do we best identify research gaps by systematically reviewing the literature, integrating patients' voices and design elements and then two inputs for eliciting the patient perspective, one directly from stakeholder interviews and one from the literature.

So, again, these reports are available on the PCORI website for anyone who's interested and it's hoped that it'll be referenced over and over

again as we build policies and plans for the future.

So, what did we do with all of that? The first step was really to deliberate and agree upon the standards using the standard template that I think many board members have seen, but basically the template was based on these five criterion. Number one, of course, patient-centeredness. So, the extent to which the standard helps us achieve the goal of respect and responsiveness to individual patient preferences, needs, and values. Of course, scientific rigor as an essential criterion. Transparency as an essential criterion, and then the empirical or theoretical basis for the standard, is it evidence-based, is it as many statistical approaches are, based on a solid theoretical framework? And then considerations of practicality, feasibility, barriers to implementation and costs.

So, again, these were the five criteria that really helped us narrow the number of standards that came out from the reports to really

come up with the list that we delivered to you.

[The archived webcast continues here.]

So, starting with the recommendations proposed by the workgroup that led to the full committee vote and then the consensus voting after that. So, we started actually with over 100 of the recommendations, got to 82, and then independently reviewed and voted on these 82, had created this rule ahead of time that if at least two-thirds of us approve that a standard was sort of ready to put forth to the Board, we would keep it in the mix and then the others we discussed.

As it turned out, we ended up discussing many of the ones that you've even had two-thirds approval and, again, submitted the final votes and brought together the final lists that you've add had an opportunity to see. And so, this is just a picture of our hardworking Methodology Committee during one of those consensus meetings where we're looking at the standards and voting on what should be in and what perhaps isn't quite ready to be put forth in a report, but it's something that may

require additional work and maybe a part of a subsequent report.

And so, through this process, we recommended methodologic standards across 10 research domains and you can see them there: patient-centeredness, formulating research priorities, heterogeneity, and you can see the rest there that you're familiar with. And I don't know if you have it with you, but just as an example, each one of these boxes has a number of standards within it, and so, as an example, one of the standards within patient-centeredness as engaging patient informants, persons representative of the population of interest in all phases of PCOR and, of course, there's quite a bit of detail in the standard and quite a bit of detail behind that in the contractors' reports and in the literature that supports how to do it and why it's important.

So, the translation table, and so, this was the place I was going to actually ask Sharon-Lise to jump in, but I don't know if she's on the line. But maybe as we're checking that, I can kind

of go through it quickly.

But the purpose of the translation table, as I've mentioned, is to map research methods to specific research questions and this is the high-level framework starting with these prioritized research questions formulating a patient-centered research question, and then creating an interface that defines the relative importance of the evidence characteristics, and I'll show you the more complex figure in a second, that helps facilitate the choices of which way to go in terms of which set of methods to employ to address a particular question, and then the translation framework, which matches the question to study design data source, analytic strategy, and there's a separate framework for different research dimensions and these research dimensions are things like is it a study on therapeutics, is it a study on diagnostics, is it an evidence synthesis?

So, this doesn't look great, which is why I had the previous slide, but it's on a much bigger piece of paper in the report, but you get a sense

from the left-hand side there where starting out with the patient question, things that are important and matter to patients, use that to formulate the research question, incorporate things like prior evidence and intent of the research decision, stakeholder perspectives, think about and incorporate specific elements like the patient population, intervention, outcomes, et cetera, and then this research framework piece in the middle that then categorizes the question according to category.

So, is this an evidence synthesis, is this a study of diagnostics, is this a study of therapeutics, and then the little picture here, if it's a study of therapeutics, then there are some options with respect to study design, some options with respect to data sources, some options with respect to analytic strategy that you're led to, and then outside the middle box, study execution, report dissemination, and as this is all moving forward, there are intrinsic and extrinsic considerations that need to be considered and there

are things like internal validity, precision, heterogeneity, data availability, all of the things or many of the things that are covered in the standards.

So, again, it's initial framework to help think through how certain questions need to be addressed in the context of PCOR, and for those of you and us who do this kind of work, this is sort of business as usual, it's articulating some of the things that we all do as researchers, but just making them clearer and more PCOR-specific.

Oh, my picture went away. I had a beautiful picture of the cover of the report there on the left-hand side. But, anyway, these are the chapters that you've all seen. Again, Chapter 2 really goes over some of the things that I've just mentioned and then an overview of the standards, and actually four to eight -- yes, thank you. Thank you. We like our cover. Four to eight are specifics of various groups of standards and you can see they align with the working groups, that the Methodology Committee sort of divided

themselves up in over the past year or so, and if you'll allow me, I'll turn it over to Bill Silberg and then we'll have a time for discussion.

CHAIRMAN WASHINGTON: Yes, but before we --

DR. GABRIEL: Oh, yes.

CHAIRMAN WASHINGTON: Before we go to questions, and I certainly want to comment even though Sharon said this would be sort of business as usual, individuals working in this field it's not.

This purpose, it's a herculean effort, and as someone who's done data synthesis over the years and had contracts to do them, I wish I had such a document available years ago, and I want to, again, compliment all involved for really the rigorous and comprehensive approach you've taken to develop what I think is really an exquisite and beautiful document because being the experts, you've really synthesized something where the whole is much greater than the sum of the individual pieces out there and I would underscore that from the

beginning, many of us felt that this report and document was for the nation, not just for PCORI, and I think that this is really worthy of representation to try to achieve that kind of ambitious goal. And so, besides congratulating, I want to go back to the question in a different context, and maybe we can address it after Bill's comment that Harlan raised.

This is particularly one that's already ready to really be the substrate for us to have some national effort to ensure that it's not only widely disseminated, but they'll be standards or adopted and used and we need to be active about that and not accept just putting it on the website. So, I'm really talking to the Board and to the entire group. I see this as just a tremendous contribution, first to our nation, but also the world. I can't imagine that anyone else is going to put up a report and it's going to be this state of the art and this impactful any time in the next decade.

So, with that, before we get to you, Bill,

Allen?

DR. DOUMA: Thank you, Gene. I want to really second what Gene just said. I have not been a researcher in the world that you guys live in throughout my career, but I'm totally impressed. I had to read it more than once in order to know what you were saying, but I was totally impressed by it and I think it's a pathway, and particularly what Gene is saying is this is something to be used by everybody, not just PCORI in our work, and we've got to figure out how to incorporate, and we've talked about it, but we don't have the specifics of how do we get there?

DR. GABRIEL: Yes.

DR. DOUMA: But I do have a little bit of a question with regard to our work, and you talk about the translational table, which I loved as an ex-engineer. I love that sort of decision tree matrix that you're putting up there.

My two-part question is: Will there be a lot of disparity between options? You say as you go down each step, there's option A, B, and C.

Will smart people disagree about which is the best option, number one? And number two, when we're asking our reviewers to rate and rank research that is being proposed to us, are we going to be able to use the transition tables to create any kind of ranking or rating for the methodology that's used in the research?

DR. GABRIEL: Right. So, just in response to your first question, we set a very high bar for the first Methodology Committee Report, and thank you, Gene. I mean, in spite of the fact that we do see this as good PCOR practice, if you will, and what's in the report is knowledge that already exists. So, we didn't create new ideas about how to do this and that, but we set a very high bar that these were things that anybody in the field would recognize as the best way to do A, B, and C. If it was something where there was still controversy, it could go this way or it could go that way, it really didn't cut the bar for being a standard.

A standard really has to be like a

practice standard or a good laboratory practice or a good clinical practice; it's something that everybody in the field, experts in the field would agree this is the way to do it if you want to answer this question. There is a whole lot of other stuff underneath that, where there is controversy and I think those are the things that we need to capture and use to inform the priority five grants, maybe we'll be able to fund a research that helps us turn that from a controversial method to a standard and it'll be part of the next revision or revision five. And so, for this document, we really set the bar very high. I think I had it in the definition something that really would be accepted by the field as the approach to answer this question.

And with respect to your second point, and Bill is going to go over that in a bit, I couldn't agree with you more. I mean, doing all of this and putting it out on the web would cut me to the quick. It really needs to be implemented and used and if there are pieces that aren't feasible or

usable, we need to fix them and that is the work that we have before us, to really hammer out the plans for how best we do that over the summer and then begin to do it as quickly as we can. I think we do need the input from the broader community before we do that, but you're sort of introducing Bill's presentation.

CHAIRMAN WASHINGTON: Joe was just saying he wanted a book for his bookshelf, and I showed him my note here saying a book.

DR. GABRIEL: Yes.

CHAIRMAN WASHINGTON: Some of you might remember there was a methodological piece that came out of another group, the Gold Report, those of you who were --

DR. GABRIEL: Oh, yes.

CHAIRMAN WASHINGTON: And it became the standard. And so, we've got to do something similar where it's the Gabriel Report, Gabriel --

DR. GABRIEL: Oh, absolutely not.

CHAIRMAN WASHINGTON: Okay. Well, Ellen, and then we got to move on to Bill.

DR. SIGAL: So, Ellen Sigal, board member.

Sherine, et al., thank you very much. I really thought that the report was very good and I actually understood it. I was quite impressed.

[Laughter.]

DR. SIGAL: So, it was really wonderful. So, my question is a little bit of a process question because the timing of the public input, the timing of the finalization of the report, and the PFAs that we want that we're advising people to follow as a guideline, how does that all work? Because it's a little confusing.

CHAIRMAN WASHINGTON: Why don't we listen to Bill's presentation --

DR. SIGAL: Okay.

CHAIRMAN WASHINGTON: That's a great segue, and then you just introduced Bill, just say his name and that was my introduction.

DR. SIGAL: Bill.

[Laughter.]

CHAIRMAN WASHINGTON: Thank you, Ellen.

MR. SILBERG: Thank you. Good morning,

everyone, and I really appreciate the opportunity to walk you through some of what we're thinking about how to take these next steps, understanding that this is a tremendous undertaking and tremendous opportunity, and I think we have a very sizable, but exciting challenge to try to do the things that we have just been talking about over time. So, I'm going to walk you through a couple of items here that you see in the book, emphasizing a few things.

One, we believe that this should be done through a phased approach. We have several different challenges and goals here, and obviously some are nearer-term, but some are clearly longer-term, and some of the things that we were just saying point to the need for an ongoing, long-term process for not just putting the report out or even just refining it, but making it a document and a resource, a reference that the community and beyond can own and use. And that will take us some time, but we do recognize that as Sherine and others have so clearly and eloquently articulated as the

ultimate goal that we're shooting for.

So, let me take you through how we hopefully get to that point, understanding that some of this is still a little bit unformed, we are trying to do things here that are a little bit different than when substantial technical reports are put out -- oh, I'm in charge of this, aren't I? Sorry. When these sorts of things are put out for comment. We're looking at doing things a little differently because we think, one, that's one of the opportunities PCORI has, but, two, we really do see this as a document for many communities to embrace and use.

So, first step, as you've heard previously, is to post the report. There are a number of refinements that are going into the document and we are thinking of this as a prepublication copy, if you will. Those of you who are familiar with what IOM does, uncorrected proofs, if you're in the publishing world, this is a document that is being put together, understanding that there's certain caveats as far

as how final it is, but it is put together in one piece for a purpose. And our main purpose in putting it out in the next ten days or so is to use as a reference during the PFA period. We reference the report in the PFAs, you've seen the language, so, we want that to be available for applicants to be able to look at. But even at the same time we understand that that's just one piece. So, that's piece number one. As that goes out and to whatever extent we begin to get input from various communities to begin to look at this, we will, of course, gather that, but this is the pre-public comment, the pre-official public comment publication, if you will.

Because we are taking the committee's charge very seriously to try to figure out ways to get broad and meaningful public comment, and I emphasize "meaningful," we need a little time to prepare to try to do that well. This is not something that is necessarily done in a standard way with things of this kind. So, we are asking for a little time to put our plan together to

define the scope and purpose of the public comment period and we also need to have in place a very clear plan for an analysis process because if you ask for public comment and you don't know what you're going to do with it, you've only done half the job. So, we see that as another piece of the element, so another element of the plan. So, that is part of our plan, to identify using probably an RFP process for a number of these pieces. How are we going to do these various things, analyze the comments that come in, bring them back to the committee and others for a revision of the initial report and then get it back to the Board?

So, as you see, some of the other elements, even as we're doing that, preparing for that, we will begin to implement the initial pieces of a communications and an outreach plan to drive the public comment. We have a number of tactics in mind. Some of them are fairly traditional; some of them may be a little bit unusual. I'll give you a couple of examples in a moment. And at the same time, we, as I mentioned, understand that this is a

longer-term engagement. So, the public comment period is only a piece.

The real heavy lift, if you will, is developing planning for longer-term outreach and dissemination so that the report is not only pushed out more broadly, but those who may not even know they need it under the general theme of why methods matter, which is something that Sherine articulated, which we just are totally stealing as the theme of this whole enterprise. We want to make it clear why methods matter to multiple communities.

So, I mentioned this a little bit and we have already started to think about this, but a couple of the elements that we believe we will need to make the public comment period meaningful will be not just getting the word out broadly, but figuring out to what extent we need to do some level of translation of the material so that it is at least understandable to some degree by multiple audiences. We know that the methodology community will get it and will be very active and probably a

number of professional organizations who have been waiting for this will jump in, but we know that there are many others for whom we need to make it a little plainer and clearer why they should care, but not just care about this, but tell us what they think. So, this is really as we've had discussions already a little bit with COEC, this is an ongoing opportunity for communications and engagement really with multiple stakeholders, multiple communities. So, even those with whom we've had official relationships for various programmatic reasons, this is an opportunity, I think, to leverage those relationships, as well as build more, all with the long-term goal in mind of working with these groups to become partners to help take ownership, if you will.

We want them to feel that this is their report, as you've said, not just PCORI's report, and as Sherine has made very clear, we want their input for refining, for improving, and for feeding that information back not just to us, but to their own communities. So, in order to do that, we think

we need to prepare a number of different pieces. You see some of them listed here and I'll go into a little more detail in the next slide. We need a little bit of time to put that together, so, we are looking at a public comment period beginning in July sometime between July 1, no later than the end of July, and, obviously, we feel time is of the essence, just as you all do. Once the report is out in the next ten days or so, we will naturally begin to get some input. So, we want to try to be prepared as quickly as we can, but we do want to be prepared to do this appropriately.

So, here's a few of the elements that we've been kicking around as what would be incorporated within the initial communications plan. Obviously, posting the report, doing a series of alerts and outreach tactics, as you see. We really want to begin to develop messaging around this theme of "Why Methods Matter" and we think that this can be done from both a professional point of view and also we think it's very important to begin to engage the patient, caregiver, and

other stakeholders in this same theme. And so, we hope to develop some customized messaging for those communities to really try to make them part of the process and not just assume that the report is too difficult or too technical. It's really our challenge and our task to make it understandable and important to these folks.

We planned a series of stakeholder roundtables and webcasts. You may hear a little bit more about that later. We see this, again, as part of our ongoing engagement opportunities. We will do as we always have, really ramp up our personal outreach by the engagement team, we will be calling on our board members and our Methodology Committee members to get all their friends and family members to be part of this process because you all have very broad and deep connections to multiple communities that we want at the table.

We also plan to target media outreach. We think that not just for the professional and trade media, but we think we can, again, using the "Why Methods Matter" theme, make this meaningful to

selected consumer media, as well, because this is part of a broader campaign to try to explain not just what we do, but why what we are doing is important for health and health care more broadly. And we're also thinking that doing some of these more traditional outreach approaches is fine, but we want to try a little bit of multimedia because there's nothing like someone talking to you in your own language about why something is important to really make you sit up and listen.

So, Sherine and I have kicked around the notion of one or more brief videos that could be used in a variety of different ways, perhaps one aimed at the professional community, the methodology community, one aimed at other professional stakeholders, one aimed at the patient and the caregiver community to explain why this is important, and we've already had some preliminary discussions about this and we'll talk about it more.

So, that's kind of the middle phase. Even as we're ramping up for that, we need to think

about the longer-term, and here you see a couple of the points that will be part of this. Obviously, we need to begin to build this plan in greater detail, working very closely with COEC, with the Dissemination Workgroup, with our colleagues at AHRQ. This is really an opportunity to tap into professional and other networks that already exist and to see what we can do synergistically because there's no point in reinventing the wheel on something that is effectively an opportunity for a professional and consumer engagement. We want to work with those who already do this sort of thing well and try to bring added value by the nature of the report and how we hope to make that report meaningful to multiple audiences.

One thing I do want to point out in the last bullet, there is always with these sorts of things a feeling that what we need is a book, and I love books, but to be perfectly honest, this is kind of my bias from my electronic publishing days, I really see an opportunity for this to be a web-based, open access reference source for multiple

communities with multiple views. If you think about just the elements that are in the draft report, it almost writes itself. You have things linking to other things, you have the opportunity for community input to help refine the various elements of the report, and I really see an opportunity for us to make a big splash here by putting an RFP together to work with a publisher, electronic publisher, traditional publisher under very clear conditions of open access because we want this to be a resource for the world to turn this into something that is really robust and will not just be posted and exist, but will be refined and improved over time.

And I'm particularly excited about that. I talked to Dr. Helfand about that a little bit. He's a journal editor like I used to be, and so, we sort of speak the same language on that. That will not be easy and it will take some time, but I think that's one of the real marks we can make in this area.

And, with that, I think I'm done.

CHAIRMAN WASHINGTON: Cards, please. We've got a few questions, and I just had one comment particularly on this approach of leveraging our partnerships and our collaborative. I would underscore that we have immediate access, just out of partners just through the Board starting with AHRQ, NIH, the Veterans' Administration, not to mention the representatives from industry and delivery systems. I know Kaiser has a big sort of research arm. I know the group with the Naomi out of --

DR. SELBY: BlueCross BlueShield.

CHAIRMAN WASHINGTON: BlueCross BlueShield has a big -- if I look around this table, there's AAMC representation, we have all these partners who should be brought in, I mean, literally immediately, and I don't know if that's in the form of simple as a conference call just to get it going. Certainly, at some point, there should be some round of face-to-face meeting, but let's not miss the opportunity to leverage what's right in front of us in terms of using those partnerships.

And Ellen's card was first, and we're just going to go this way, if you don't mind. So, Ellen and then Arnie and Michael and --

DR. SIGAL: But I still don't think I have --

CHAIRMAN WASHINGTON: Give your name, please.

DR. SIGAL: Ellen Sigal, Board.

I still don't think I have an answer to how this works with our PFAs because the way I look at this is September, maybe we'll be finished, October, and our PFAs at that point will be reviewed. So, I guess the point is is this is just a guide. So, ultimately, we're telling people to pay attention to this draft and that's what it is because we're not going to have anything close to final. So, if there are substantial changes, it's just too late for a first draft. And that's okay, I'm just trying to connect the dots.

MR. SILBERG: I'll let Joe --

DR. SELBY: That's absolutely right. We point applicants in our application guidelines. We

point them to the report, but we make it very clear that in this first round, they are not formally held accountable for the standards in the report. We just want them to see it because we want good PCOR.

CHAIRMAN WASHINGTON: Arnie?

DR. EPSTEIN: Arnie Epstein of the Board.

I'm going to try and pick up just briefly on your theme about leverage. I was impressed that when the major journals all got together and said they won't publish an article unless it was listed on ClinicalTrials.gov, we immediately saw articles get listed on ClinicalTrials.gov. And it strikes me that when I think of the people who can drive this system, it's the funders, and, Gene, you were quite right to name them right off, from NIH and ourselves and the Robert Wood Johnson Foundation and I won't name the top 15, but you get a sense, and then it's the major journals.

And if those two groups said you will not have money to do research or you will not be able to publish your research unless it meets these

standards, I think you'd be 97 percent of the way there with just that. So, it's not a general outreach program that I think you need to go to. There are people who control the spigot.

MR. SILBERG: That's an extremely good point, and it fits into some other journal-focused approaches that we have in mind for some of the other work that we plan to fund. So, I think it's a good point to start sooner rather than later.

DR. EPSTEIN: Yes, they're secondary to things you have to do to actually bring it into practice like you might put a series of workshops out for all the major clinical, national meetings, which will help people become more aware of these and institute them more effectively, but the guts of this is will I or I won't, it's got to do with funding and publication.

CHAIRMAN WASHINGTON: Michael?

DR. LAUER: Mike Lauer. I'm a member of the Methodology Committee, but today, I'm sitting in for Francis Collins of NIH.

So, I have a question of clarification,

Bill. What is happening during the Month of June? You said the comment period is going to start in early to mid-July, and is that a period where there will be an opportunity for some further review and perhaps some revision before the comment version actually goes out?

MR. SILBERG: That's probably something we'll have to talk about more with the committee. Most of what we planned to do in June is to prepare a variety of support materials and some of the other communications pieces that you saw for the public comment period itself. But I would certain defer to Sherine for that ongoing discussion.

DR. GABRIEL: So, I would actually say yes. We want comments whenever we can get them, and so, if there are comments in June, we may not have the perfect tool to capture, categorize, whatever, but we need them and want them as soon as they're available. So, yes.

MR. SILBERG: And this also goes with the notion that it's very important for us to have a very clear comment gathering and analysis plan in

place because I think Sherine's right, you will want comments whenever they're available. The task will be to be sure that they are appropriately put into a process so that they are systemically reviewed and fed back into the revision process.

MS. HOLE-CURRY: Leah Hole-Curry, Board Member.

I guess just a comment and a question about especially the public comment and dissemination process. I think that it's really important for us to begin with the end in mind, and that doesn't mean we wouldn't take any comments and try to make it as accessible as possible. So, I appreciate those elements, but unless we know what it is we're trying to derive from the public comments, I think we're missing an opportunity here, and I don't hear that yet and I'm not sure how to get at it.

I don't personally know the answer, but I was reminded of AHRQ's good work about "Ask Me 3" or ask three questions. They didn't go out and try to translate patient or hospital safety reports in

a plain language for consumers to then use with hospital administrators or something else. They derived a campaign that translated it back into what was important at the time they were there and I would suggest that we include in this planning a framework for what we think are public commenters, what are the essence of those three or what is the end that we want to get out of it? And we'll learn a lot more and that's fine, but if we don't have something like that in place, I think we get a lot of broad comments which are great and the more that we can talk with people about why methods are important is also great, but we're missing an opportunity.

So, it's kind of I asked for the time and I get the explanation of the watch. Well, actually, consumers care about the watch if it's solar-generated and they need to be somewhere where they don't have access to a battery or something, but it's explaining the components that they care about and why they might care so they can help inform the choices.

DR. GABRIEL: Yes, that's helpful and actually, those examples are good, but that answers Mike's question in part because that is some of the work that we're going to do in June.

MR. SILBERG: Right.

MS. HOLE-CURRY: Right.

DR. GABRIEL: If we were just going to say here it is, tell us what you think, we could do it tomorrow.

MR. SILBERG: Right. Well, maybe the day after.

DR. GABRIEL: But that's why we need the time in June to build those tools.

MR. SILBERG: No, that's right, and you'll recall, I started off by talking a little bit about the need to define the purpose of the public comment period and process.

MS. HOLE-CURRY: Great.

MR. SILBERG: Yes, you're right on the money.

MS. HOLE-CURRY: Great. And just reflecting Arnie's comments, as well, I mean, I

think the majority of what we can do for levers here is really in terms of financing things that are in line with the standards as we continue to iterate them.

DR. GABRIEL: Yes. That's extremely helpful. In fact, we probably need to have a face-to-face meeting with some of those major levers, funders and major journals --

MS. HOLE-CURRY: I agree.

DR. GABRIEL: -- sooner rather than rather than later to really learn from them and figure out how we can better engage them going forward.

MS. HOLE-CURRY: I agree.

CHAIRMAN WASHINGTON: Gail?

MS. HUNT: Yes, Gail Hunt, Board Member.

I just wanted to remind you guys that I think that the COEC is a committee that actually needs to be really involved especially because we're talking about getting down to the level of patients and you didn't mention that. So, I just wanted to be sure that that's an important part of what's going to happen.

MR. SILBERG: Yes, that actually was in one of the bullet points. I may have passed over it speaking, but we see close collaboration in working with the COEC, who we have spoken to about this on a couple of calls so far in its formative stages, as well as with the Dissemination Workgroup and our colleagues at AHRQ, is being elemental to making this work.

DR. GABRIEL: And if I know Sharon, we'll come at it when it goes around, but Brian Mittman that serves on the Dissemination Workgroup within the COEC has actually developed this sort of implement -- with the COEC team and the staff has started to write what the Dissemination Implementation Plan ought to look like. So, I think that engagement is happening.

CHAIRMAN WASHINGTON: [Off microphone.]

[Laughter.]

MS. HUNT: Brian Mittman, as far as I know, hasn't been on the COEC calls on an ongoing basis.

DR. GABRIEL: I'm sorry, on the

Dissemination Workgroup of the COEC?

DR. SELBY: Well, it's --

DR. GABRIEL: Or is that no --

MS. HUNT: No, that's a separate group.

DR. GABRIEL: That's not happening.

DR. SELBY: It's separately of the COEC.

MS. HUNT: That's a separate group.

DR. SELBY: It's not of the COEC.

DR. GABRIEL: Oh.

DR. LEVINE: I think the intention may be there, but there has been no connection.

DR. GABRIEL: Okay, well, that's good to know.

MS. HUNT: Yes.

DR. GABRIEL: Thank you.

MS. HUNT: Okay, that's why you had the puzzled look.

CHAIRMAN WASHINGTON: Thank you, Gail.

MS. HUNT: You're welcome.

CHAIRMAN WASHINGTON: Rick?

DR. KUNTZ: Yes, Rick Kuntz, Board Member.

First of all, I think this report's great

and I was trying to understand how we should position. I think it's important to actually position this report on a spectrum of what a Methodology Report could be for the public so that we don't get a lot of outlier comments that may not be relevant. This is not a handbook of methods and let's make sure we understand that. So, for methodologists who are looking for handbook-type information, they're not going to get it and we don't want to be that.

What this is, is an outstanding report by 17 great and maybe more methodologists who have condensed what they think is really important for the people who are going to do PCORI research, and we have said the whole time that this is about bringing more stakeholders who aren't classical methodologists, classical researchers into more meaningful research so we can address unmet needs by patients. This helps to guide that and there are some areas that are very high-level, some that go down a little bit lower, but they basically ask researchers to pay attention to these standards,

these principles, and engage methodologists involved in the process.

So, somehow, I think we should say this is what this report's about, at least my viewpoint on this or maybe you have Sherine come back. That way, we can get a more meaningful understanding of what the public's reaction is to this as a guide for high standards and how to integrate better methodological resources into your research. And I think it's pitched just right, but we need to position that. Thanks.

DR. ZWOLAK: Bob Zwolak, Board of Governors.

My comment's been a little bit off what Rick just said. I expected before I saw any product a tiny bit more of a cookbook of methods, but, in fact, what I see is something at a much higher level and I do think that there's a nuance between methods and standards for methods and I think this product is spectacular and when I think about the buzz line "Why Methods Matter," I love it, but, in fact, I think it's even more important

that we have standards for the methods and I do think as we present this to the public, this is more standards for the quality of research that we expect rather than sort of a little bit lower level of cookbook of methods and I think it's important that we present it that way because that's what our Methodology Committee has seen as more important at this point.

CHAIRMAN WASHINGTON: Okay. Just to keep this group alert, not that I need to, I'm going to shift the direction.

Carolyn?

UNIDENTIFIED SPEAKER: Oh, my God.

UNIDENTIFIED SPEAKER: Oh, no.

[Laughter.]

DR. CLANCY: This is are you paying attention to the comments, and yes, I am.

[Laughter.]

DR. CLANCY: First, I want to say congratulations. Congratulations and good luck.

[Laughter.]

DR. CLANCY: Because having done

phenomenal work, I think you're going to get an immense amount of feedback, which is exactly what you want at least in theory, but sometimes in reality, processing that can be challenging. So, good luck.

I have a question about when you're planning to brief the Hill. I mean, this is actually a statute. It is autopilot for Institute of Medicine Reports, and I don't know to what extent you were able to get feedback from the Institute of Medicine people who wrote the one on systematic reviews to get a sense of what feedback they got from the Hill because that was also legislatively mandated in the Medicare Improvement for Patients and Providers Act, known to us fondly as MIPPA, in 2008. So, they are very, very important constituency and I want to underscore everything Arnie said about journal editors because they're a very, very important driver here.

The other thing that I might recommend, I have an enormous amount of confidence in Kerry Barnett and other people on the Board, but if I

look at who's going to be the major funders for PCORI, starting in 2013 and out and beyond, I think special outreach to self-insured employers and insurers would be a terrifically good idea and I'll leave it at that.

CHAIRMAN WASHINGTON: Debra and then Gray, and the rest of you have to wait to decide which direction we're going to go.

[Laughter.]

DR. BARKSDALE: Well, first of all, I was one of the people charged of volunteering and I'm not sure how it happened, but, anyway, with doing a more thorough reading of the report and I have posted my comments. But I do want to make sure that we hear what both Rick and Bob said about this not being standard and not handbook of methods because, honestly, when I started reading, I was confused and I didn't understand what I was reading and I didn't understand the audience, who this was intended.

I came to realize that the less I knew about a topic like when you got the Bayesian, and

then it seemed like just fine. But I do want to reiterate that I think it's really important that in whatever PR work is done that it's clear what this document is or people may be somewhat disappointed.

UNIDENTIFIED SPEAKER: [Off microphone.]

DR. BARKSDALE: Yes.

CHAIRMAN WASHINGTON: Gray?

DR. NORQUIST: Gray Norquist, Member of the Board.

So, I wasn't one of the four, but I wrote comments anyway. So, I think I had the same feeling. First off, we don't have an Executive Summary, which we need desperately in order to really put it into context that we're talking about.

I disagree a little bit. I mean, I think it is a set of standards and I think in the legislation, there actually was more asked for. So, I don't think we're off the hook for eventually getting to some of the controversial issues. I mean, people are really looking for that and I

think they're going to look to us at some point to really set that and I think it's okay to start this way. Let me just say I said that in my comments that it's good to start with the standards, kind of lay out the big picture, but at some point, we're really going to have to get into the dirty details, going to have to make some pronouncements because that's really what people are going to want to see and it's nice to put the standards up and I'm sure all the editors and stuff are blessing stuff because it's at this level, but it's really at that lower level and where some of the controversy is that we're going to have to weigh in that it's really going to make a difference in what people fund and then what's going to be research.

So, when Bill was talking, I had this idea that, I mean, it's a great idea to have an online thing that's kind of like a Wikipedia that at least you have control of that you can get that coming in and you can have it as an ongoing kind of way at looking at changing this and having that kind of ongoing controversy in the field. I love paper,

but I'm kind of getting away from it because it's not real-time. I mean, it's this kind of stuff that could be ongoing. And so, I would just think in that direction and it'd make me feel better about this report to say we're here, we're going to move there at some point, but that's the direction in which we're going. You know what I mean?

DR. GABRIEL: Yes, no --

DR. NORQUIST: I think an executive summary that laid that out and put it, I think, would help a lot.

And let me just say the only other thing is it's not perfectly standards because there is some specifics in there. So, that also is what makes it a little confusing. If you really want a full standard, then make it that way, don't have it written where you've got some other stuff you kind of snuck in. You know what I mean?

DR. GABRIEL: Yes, yes.

DR. NORQUIST: Okay.

DR. GABRIEL: No, I think you're exactly right and I really appreciate the comments by Rick

and Arnie and actually the chat with Harlan on the same topic. Upfront position is what it is and what it isn't and you're also exactly right, we focus on the standards because we needed to get those right, we needed to spend the time devoting in all of that stuff that you saw if those were going to be standards by which our applicants are going to be held to. We wanted to be sure that was really the first most complete product, but we actually see three pieces.

So, there's the standards, there's the report that has all that other stuff in it that hasn't had as much opportunity for review as it will and then the recommended action. So, I almost see kind of three things with the standards being what we led with and you're absolutely right, we have to build out the other two pieces and we'll just have to begin to do that over the summer with help of many around the country.

DR. NORQUIST: But would you agree at this particular point in time the standards -- you would expect that people would at least address the

standards if they submitted an application at this point? I mean, is there anything controversial about --

DR. GABRIEL: Oh, absolutely. That's why we led with that, and so, now the timing to get Ellen's point, the timing isn't perfect, we can't ask them to address the standards when we put out the RFA next week, but that's exactly the plan and that's what the statute sort of tells us to do, develop these standards, put them up for public comment, finalize them, have the Board approve and adopt them, and that adoption step I think means exactly what you said, that means that applicants will need to comply with the standards in order to be funded and that's the other reason we kept them at a very high level and kept all the controversial stuff away from that. It's not a debatable point whether you should or shouldn't do this, it's something that the community all agrees is the way to go.

CHAIRMAN WASHINGTON: Okay. Leah has a question and then we'll go to Ellen.

MS. HOLE-CURRY: Back to this point, I really kind of wanted to understand that. I guess I was seeing this as a foundation and based on the criteria that you set up, if we release PFAs in the way that we have drafted them, our reviewers are looking to see whether these standards are met. So, we are actually funding and applying them, even if they will be added to, adjusted in the future. Am I off base because what I thought I heard is no, we're not going to hold them to that, and, actually --

DR. GABRIEL: I'll maybe defer to Joe --

CHAIRMAN WASHINGTON: Yes, I guess I'm confused. Let's let Joe answer this.

MS. HOLE-CURRY: Okay. Or maybe it's a later discussion of the PFAs --

CHAIRMAN WASHINGTON: No, no.

DR. SELBY: Yes, we were going to touch on it, the PFAs, but, as I said, this round, we are saying very clearly and we've modified it recurrently over the last week to make it clearer and clearer that these are draft standards, they

have not been adopted by the Board, and, therefore, applicants are not held accountable.

MS. HOLE-CURRY: I guess I don't get that though. Are we going to instruct our reviewers to look at those standards and see whether the applications utilize or reference those standards?

DR. SELBY: We can't this first time.

MS. HOLE-CURRY: I disagree --

DR. SELBY: I would say that because a lot of them are, as Sherine has noted, good practice, good research practice already, I think reviewers, many of them will know what is good research practice and what's not. So, if you do something that transgresses the standard, you may get marked down in the review not because it was a standard you failed to adhere to, and so, you didn't get the box checked off, but just because it makes it not a good study and it's pretty good common knowledge that it's not.

CHAIRMAN WASHINGTON: Okay. Can we take this question up again when we get to the PFAs?

DR. SELBY: Yes.

CHAIRMAN WASHINGTON: Because it's not clear to everyone, and so, we are going to come back to that. And I'm going to go to Allen and we are going to go across. Steve, you got the last word on this one today.

DR. DOUMA: Yes, I'd just to comment on the communication elements, the plan elements. We have a couple of pages of those elements. They are pretty generic. Pretty much any report of any substance, we would look at those channels, which is basically what we've laid out as a bunch of channels. What we don't yet have is a strategic communication plan which has goals, objectives, timelines, measurable stuff, and then we can decide which channels we focus on and we've got a budget and prioritize and we need to do that based on our goals and objectives and our timelines and I would suggest and it'll be an actual sort of thing and I know Bill is sophisticated in this, is that as we develop this communications strategy for the immediate feedback over the next four months, actually, it's the beginning of a five-year plan

and we need, obviously, to build on that first four months, but we need to do that a priori, we need to have that in our plan before we start.

CHAIRMAN WASHINGTON: Harlan?

DR. WEISMAN: Harlan Weisman, Board Member.

I won't repeat all the very auditory comments that you received, which I agree with. I just wanted to read through comments and maybe a couple suggestions. First of all, Sherine alluded to it. I did talk to Sherine earlier and Arnie and Rick really set me straight last night about what this was all about and it was extremely useful for me and it sounds like Debra went through the same thing and Bob went through the same thing. And so, if board members are there and we're in the know, it just reinforces that message and in terms of sitting context, I think Rick and Arnie were able to do it for me within a two to five-minute conversation, so, I think they could be helpful, perhaps, in helping the committee think about how to do it.

I wanted to talk about two stakeholders that might be important to engage that are involved in this field and I've brought up one of them in the past and that's FDA. And you talk about FDA in the premarket approval process of randomized clinical trials for approval, absolutely the case, and here you're addressing in some cases post-marketing. FDA's highly involved in post-marketing studies and also the expansion of indications and safety observations in which the relevance of this is highly important not only to FDA, but also to industry, which I represent, and it would be not good if there were multiple standards out there. The PCOR-PCORI standard that we think is good and then there's another standard that FDA is following. So, I think getting them involved and aligned or at least reading it and having them participate would be very good.

And then the other one, and you do comment in there in the document about it's not about quality standards, it's about these standards of what you should expect out of a report or a

research to judge the quality of the researchers who designed the research, but you're on the National Quality Forum Board, but in looking through the things they are doing, they're addressing many to these very same topics. One that came to mind when I was reading your report was on PROs, Patient-Reported Outcomes. NQF has got a whole initiative around PROs and is, in fact, having a workshop or something in the summer on PROs and it just seems like another opportunity to get us aligned.

I know, Joe, I believe you and Anne had a meeting with NQF recently, but it's just another aligning force.

I want to go back about the topic I brought up at the beginning and other people have reinforced this need to how do we report this stuff to the world? Even immediately, Bill, when Sherine mentioned the availability of the 15 reports, whoever it is, on the website, I immediately want to go look and see how easily I could find it and I use the site a lot. It's not easy to find. It's

under "About Us." Now, why you would look for publications under “About Us.” So, you go “About Us,” then you go to “Methodology Committee,” then you go to “Research Methodology,” and then you go to “Contractor Reports,” and then you find it. and we need almost immediately a publication section on the website where you could look at publications.

I love the idea of what you're talking about on this open access reference source, I may be old-fashioned and I use the web a lot, but I still like to hold things in my hand when I want to learn about it and read it and particularly a reference source. So, while it’s available and if in completeness because I do think you need the appendices and other parts and I would suggest you also need those underlying contractor reports if you really want to get into it. That’s going to be hard to do on a screen. I think we should think about actually -- it’s not an “or,” I think it’s an “and.” And maybe we need to charge a nominal amount to cover publication costs. We give people the choice. They can get it for free off the web,

print it on their own printer if they want, or for a nominal fee, we give them a book. So, that was one suggestion.

And then another source for feedback that I think would be really interesting and it's getting into that debate that I didn't know existed, on the PFAs and how they use it, I would certainly use the people participating in the PFA process, the reviewers, the respondents to the PFA, the people writing grants and ask them was this helpful to you or not? Because that's real-world use, that's real-world experience with these standards. It's our first test of the standards, even if they're draft; we're expecting people to at least look at it. I think that would be wonderful to find out how it performed in the real world.

And then, one last thing and we don't have to talk about it now, but I really liked you had a very clear method of driving consensus in the way you came up with this, and I'm wondering and you can talk to me about it later or not, is there any lessons learned from how you guys did this? I

mean, you had to come up with a process and maybe you would always do it that way, maybe you would do it a different way, but as a learning organization, I think it would be a scientifically-driven organization that is going to be driving things to consensus. I think it would be valuable to learn from what the Methodology Committee did.

DR. GABRIEL: So, and we can discuss that in detail at another time, but there were lots and lots of lessons learned, but I'll just mention one of them being that even when we all agreed on the templated, structured, voting forum and we got together and talked, we realized that we didn't really agree in the same way. So, agreement wasn't always agreement and you can't replace the face-to-face discussion and debate, but, yes, it was a learning experience.

CHAIRMAN WASHINGTON: Okay. Sharon, but before you go, I want to underscore the point that Harlan just made regarding PCORI being a "learning organization." I think we should have this as a deliverable in each major undertaking where, Joe,

we'd be looking for you and the staff involved along with the respective committee and/or board members to report out what was -- I'd be looking for what was the number one lesson learned. There may be others, but it allows us to focus because I suspect we'll eventually discover that it's a core set of sort of approaches and/or activities that when followed as best practices, really allow us to be a step ahead of what we would have been going into the room just based on our own learning. So, and we need to find a way to really be explicit and visible about this so it's a very important point.

DR. GABRIEL: And if I could just add to that, I just remembered what I've asked Deloitte to do because I'm afraid that we will lose it, is to create a step-by-step sort of operations manual describing what we did in a very detailed way so that we can go back through it and before they leave us we can go back through it and kind of have that discussion about what worked, what didn't work, if we were to do this again, how would we change it, and really capture those learnings.

CHAIRMAN WASHINGTON: That's great. Thanks.

Sharon?

DR. LEVINE: Again, I won't repeat the congratulations --

CHAIRMAN WASHINGTON: Just repeat your name, please.

DR. LEVINE: Oh, sorry, Sharon Levine, member of the Board of Governors.

UNIDENTIFIED SPEAKER: Woman of the Year.

UNIDENTIFIED SPEAKER: Woman of the Year.

DR. LEVINE: Woman of the Year.

CHAIRMAN WASHINGTON: Woman of the Year.

DR. LEVINE: I'm not sure which year.

[Laughter.]

DR. LEVINE: I had a couple of comments. One, in terms of the research that will be produced using the methods that meet these standards, there's sort of two universes: one is the universe of producers of that research and the other is the universe of consumers. And I do think we need to thoughtful about so, who from the consumers of the

research which will be influenced by the standards? I think there is a great opportunity here for curriculum development under the theme of why methods matter for medical school, for residency training programs, for continuing medical education, the extent to which clinicians are able to bring a critical eye to what they read and what is produced in terms of research, can actually help on the ground to advance in the evidence basis of practice and I do think there's a great hunger for that, particularly among the medical students and residents who ultimately do research and are kind of thrown into it headfirst, oftentimes, without a lot of grounding.

Bill, I had a question for you. There's a statement in -- the pages aren't numbered, but under “Elements of the Implementation Plan” --

DR. WEISMAN: Thirty-one.

DR. LEVINE: Huh?

DR. WEISMAN: It's 31.

DR. LEVINE: Thirty-one. Oh, it’s very small, sorry. Thirty-one. Adherence rates,

publicized adherence rates, and I just wondered what your thinking was around that.

MR. SILBERG: I'm trying to remember the context I'm looking at, Sherine, because I think some of this was based on some discussions that we may have had earlier. But I think we were -- weren't we talking about adherence to standards?

DR. WEISMAN: Oh, and do the studies adherence?

MR. SILBERG: Yes.

DR. LEVINE: Is it PCORI-funded studies or the universe?

MR. SILBERG: Yes. Well, I think it would be an interesting project to look more broadly as a research project, but I think we would probably want to start with our own stuff.

DR. LEVINE: Okay, so, there's nothing more than that in there?

MR. SILBERG: Not at this point, I don't think.

DR. LEVINE: Okay.

MR. SILBERG: But since you raise it, if

we're talking about ongoing adoption, ongoing uptake, as well as trying to use the leverage we have to try to make things change, then that's sort of a metric, could be rather powerful for our own work as a start.

DR. LEVINE: Well, and that would tie back to Arnie's comment about --

MR. SILBERG: Yes, that's right. That's right.

DR. LEVINE: -- journal editors and funders.

MR. SILBERG: And funders, yes. Yes.

DR. LEVINE: Exactly. And then just one --

CHAIRMAN WASHINGTON: And, Sharon, just on that point, I mean, as an example, when the "Gold Report" was published, along with some fellows, we used it to go back and look at the literature over the last 20 years and we saw curves that showed that 20 years ago, those decision analytic CEA standards were low and they just continued to go increase and then we literally segregated by

different journals and different discipline areas. And so, you're right, we just have a great substrate here to play with and go back to --

DR. LEVINE: Right. Right, which might --

CHAIRMAN WASHINGTON: -- that can be leveraged in so many ways. And so, we may be applying to PCORI, but others creatively are going to look at that's what we want to do going back what Arnie said, working with public --

DR. LEVINE: Which might be an interesting contract after November, which should be the contract with someone to actually do a five-year review of the literature to establish a baseline from which to measure the impact of the standards going forward.

DR. WEISMAN: That's another place where NQF might be an interesting resource for us because NQF does look at adherence rates and they see exactly what you said, which is when you start measuring it and you start saying it's a standard, people start doing it. You can see it rising, but they have a lot of experience on how to measure

this stuff.

DR. LEVINE: And just one final comment, which is when the final approval and publication of the report in November, I think it would be helpful to position this in the context of the next set of work of the Methodology Committee so that we address any illusions, as you said, that this is finished, this is done, we've reached the end of the journey, but certainly about the next iterations.

MR. SILBERG: Yes, and that's an important message that we should really use to frame all the work we're doing here.

CHAIRMAN WASHINGTON: Okay. Last word.

VICE CHAIRMAN LIPSTEIN: Thanks, Gene. So, Gene. As you know, I come to this assignment as one of the Board's representatives of hospitals and health systems and large aggregations of clinicians who may or may not be researchers. I can't wait to be in my next presentation with you where I use terms like heterogeneity of treatment effect.

[Laughter.]

VICE CHAIRMAN LIPSTEIN: Or instrumental variables which don't mean musical instruments.

[Laughter.]

VICE CHAIRMAN LIPSTEIN: So, coming as a non-researcher, I read this and I have a specific suggestion, Sherine, at a high level and I'm going to give two detailed examples, and this for the Methodology Committee with a lot of help from staff to host some invitational meetings or conferences around specific topics that are in this report and the two that I got most excited about when I read was on page 75 of the actual report with the beautiful cover is the section on data networks as research-facilitating infrastructures.

And so, I was thinking that lots of health systems or hospitals or groups of hospitals would love to know how to put together those data networks and if they could do that under guidance of the Methodology Committee, standards set by the Methodology Committee so that these data networks really were robust enough to be facilitating agents

of PCOR, that would be a terrific way not only to engage my community, but to have something that's in the Methodology Report to help with its implementation. And, perhaps, Joe, we could even think of some day in the future where we would fund the creation of those data networks as a way to do that.

The second example I would give is an invitational meeting with non-research clinicians on the whole subject of missing data. As Joe was explaining to me earlier today, missing data can cause a specific research study to lack validity, but among clinicians, even if it's valid, it can cause it to lack credibility because that missing data says you don't know enough about me as an individual to access my outcome, to understand my outcome, and so, I think there's been a big chasm between comparative effectiveness outcomes research and clinicians because clinicians don't necessarily believe that you understand the nuances of their patient population and they usually attribute that to missing data, whether it's missing data about

real-life circumstances that isn't clinical data or data that is clinical. And so, if we could have two or more invitational conferences that make the Methodology Report come alive.

And so, speaking, if anybody's listening, from the hospital health system community, go right to pages 70 to 80 because that's where these two topics are described, I think it'd be a great way to make this report meaningful and then get useful feedback and also implement at the same time.

So, Mr. Chairman, thank you so much.

CHAIRMAN WASHINGTON: And I want to say thank you to all the Board members for --

DR. CLANCY: [Off microphone.]

CHAIRMAN WASHINGTON: Please.

DR. CLANCY: Sorry, Carolyn Clancy, Board Member.

And I just wanted to add one other thought fragment. When Sharon started talking about curricula in training, where I think thought you were going was actually for reviewers because in some way, adoption will be easy to access because

once this is finalized, this is like an IQ test. No, I'm serious, and the Gold Report saw that, as well. People referenced it all the time. Now, whether they actually adhered to the recommendations was left to something else. Ultimately, that plays out in journals in a variety of venues, but reviewers for investments that PCORI will make, including patient reviewers, I think is going to be really for that, we want meaningful adoption, not just the citation, yes.

CHAIRMAN WASHINGTON: Okay. Thank you, and, again, thanks to all the Board members. This has been phenomenally a rich discussion and I think our new colleague, Rachael Fleurence, who's the expert, has a Ph.D. in value of information would agree that this has been from a value-added perspective a major contribution. So, thanks.

Here's where we are. Harlan, I can tell you one of the lessons I've learned since I've been on this board is that despite what you may think about our framers, when you have a firm deadline for delivering something that's legislated by

Congress, you deliver it. And so, in this case, I want to remind us that this report was due to the Board and arrived officially on May the 10th. And so, here is, again, tremendous creativity stemming from just a little pressure, Sherine, on the group.

And where we are now is essentially, as a result of today's discussion, just for the record, I'm going to ask that we accept the report, because it doesn't ask that we adopt it, that we accept the report, also with the understanding that the plan is that in accepting the report, we are going to proceed eventually to a public comment period and, importantly, we are going to conduct some work in the interim until that period to ensure that we get at the questions that Leah raised regarding what is it that we want from the public and what's the best way to garner that information? And then with all the additional information, we would come back to the Board with the revised report for a vote on official adoption of that as the Methodology Report. Pretty clear?

DR. WEISMAN: Okay, clarification. So,

we're accepting it, but there's also this plan to publicly post it --

CHAIRMAN WASHINGTON: Oh, absolutely.

DR. WEISMAN: And the only thing I would suggest, and maybe it's just trivial, is that the suggestion by Rick and several others that there be somewhere as it's going up a little context setting. It doesn't have be a lot, but maybe like a half page of this is what's in here, this is why it's important as opposed to just putting it there so that you avoid what Debra and I and Bob and others -- have to have context setting to help.

CHAIRMAN WASHINGTON: Okay. All in favor?

[Chorus of ayes.]

CHAIRMAN WASHINGTON: All opposed?

[No response.]

CHAIRMAN WASHINGTON: Any abstentions?

UNIDENTIFIED SPEAKER: You didn't have a second.

CHAIRMAN WASHINGTON: Oh, thank you.

UNIDENTIFIED SPEAKER: Just in case.

CHAIRMAN WASHINGTON: Can I have a second?

UNIDENTIFIED BOARD MEMBER: Second.

CHAIRMAN WASHINGTON: All in favor?

[Chorus of ayes.]

CHAIRMAN WASHINGTON: All opposed?

[No response.]

CHAIRMAN WASHINGTON: Any abstentions?

[No response.]

CHAIRMAN WASHINGTON: Okay, so, just a round of applause really for -- thank you.

[Applause.]

CHAIRMAN WASHINGTON: Oh, you still have a presentation?

DR. SELBY: Three minutes.

DR. GABRIEL: I have a surprise, you forgot --

CHAIRMAN WASHINGTON: Oh, that's right. Oh, you can't go. Just go to the --

DR. GABRIEL: I have one slide in my surprise.

CHAIRMAN WASHINGTON: I'm sorry, we have a surprise. We have the time left.

DR. GABRIEL: You'll have to let me know.

So, this is just my last slide and, first of all, before I talk about this, thank you for this discussion. I mean, I was writing furiously as others were, and we got lots and lots of good ideas. We thought we had some pretty good ideas, but what we needed to do in the summer and we've got many more. So, I'm very grateful for that. And when we look ahead, we see some of these things that you all mentioned, creating different versions, different tools, maybe different views for various stakeholders. Again, the Methodologic Research Agenda.

So, we learned a lot putting this together that, hopefully, we'll inform that, we'll be updating things, we will be doing the work over the summer, as you all saw, and we will be hosting our own little retreat to figure out get these ideas and put them together with ours and figure out just what we're going to do, how we're going to reorganize ourselves moving forward, the workgroups that you've all seen will disappear and we'll reorganize ourselves in a different way and it will

probably be aligned with -- and you'll hear about this later in the strategic plan discussion, the strategic priorities under the methods, and one of the strategic priorities -- I keep looking at Sharon -- really has to do with training, education of a whole variety of stakeholders. So, how can we facilitate that? And I think that is an important future step.

And then pulling together a whole bunch of different advisory groups, outreach. And, of course, working with all of you on the first PCOR conference. So, it's not like we're going to run out of things to do anytime soon.

So, before my surprise, I mean, we have so many people to thank, it would take a whole other hour. We've had very good luck with the principle investigators and research team members that you could see just all listed there, we're very grateful for the work of the Editing Team and the Interim Researchers that we pulled in just a few months ago and I think Andrew might still be here, but Heidi, Annette, Tim, Howard, Justine, and

Crystal were incredibly helpful along the way. I didn't name names here, but especially Gail, who I don't think sleeps because no matter what time of day or night you send her an e-mail, you get something back within minutes, it seems. So, Gail and Laurie were incredibly helpful to us along the way, and, of course, Joe, but really many, many of that PCORI staff really pitched in and I don't have them listed here, but, of course, the Deloitte staff have been very supportive and very helpful, Anna, Constance, Anisha, Millie, the whole group. So, we've had an enormous amount of support and we're very grateful for that and thanks to all of you for your help.

Now, for my surprise. I hope I don't get laughed at or something, but, frankly, in my position, I had a rare opportunity to watch how the members of the Methodology Committee came together to do something that really seemed impossible for a lot of people who looked at that legislation and pulled together as a team and it was really an inspiring thing for me to watch and they inspired

me to create a little video that nobody has seen. Now, in case you're worried about PCORI resources, these are Sherine resources that went into putting this together.

[Laughter.]

DR. GABRIEL: And I kind of pulled Sharon-Lise into the process. It's only three minutes, but I think it will give you a sense of what I see inspires the Methodology Committee members and to thank them in public. So, let's see if I can make this work.

[Video shown.]

[Applause.]

DR. WEISMAN: You're hired.

DR. GABRIEL: So, anyway, I didn't think a simple thank you would be enough. I know a lot of them weren't able to be here, but they're all watching and they'll all get a copy of this and it was a remarkable effort and it was a wonderful thing to watch.

CHAIRMAN WASHINGTON: Wow.

[Archived webcast breaks here.]

CHAIRMAN WASHINGTON: After such an uplifting, inspirational morning, I think we should just break and not come back.

[Laughter.]

UNIDENTIFIED SPEAKER: Is that a warning?

CHAIRMAN WASHINGTON: It's going to be tough to beat this.

DR. GABRIEL: That's right.

CHAIRMAN WASHINGTON: I'm looking at Leah and Melissa and forget about it. Anyway, we're going to have a break. We're going to take up to 15 minutes [off microphone]. Come back at 10:55.

[Recess.]

CHAIRMAN WASHINGTON: And we're live. Welcome back, everyone, to this meeting of the Board of Governors of the Patient-Centered Outcomes Research Institute.

Now we're going to take up the topic of strategic planning. Many would argue that we've been undertaking strategic planning since September 23, 2010, and in many ways have. Over the last I would say year, we have begun to focus increasingly

though on what our strategic imperatives at the highest level and we began to have discussions about what's the sort of overarching framework within which we could organize all of our PCORI activities with the idea being that we needed some higher-level working roadmap that help to guide our activities from day to day and allow us to be able to connect the various pieces and some simple, but yet comprehensive and integrated way.

And with that in mind, a couple of months ago, the Board had a discussion in which it underscored the need for us to develop the equivalent of a strategic framework or a preliminary strategic plan that would begin to pull everything together that we're working on now as well as provide the outline and/or framework for our plans going forward. We decided that this would be a board-level activity that would be directed by me in my role as chair of the Board, but also in partnership with Dr. Selby as the executive director of PCORI and we also formed a working group which was really charged just to

brainstorm away from the Board about what this framework might look like and eventually this working group established a draft which we've had some input on from the Board and with an input have now developed what we see as the preliminary strategic plan for PCORI.

I would underscore that there is nothing new here in terms of content per se. What's new here is, again, the framework that becomes really an organizing instrument for us and a way for us to -- it's a document for us to look at as we think about any presentations, as we think about what's ahead. In the same way that we've had some board members look specifically at other reports, including the Methodology Report, I want to acknowledge that in this case when we had to draft eventually, we asked Harlan W., Rick, Freda Lewis Hall, who's not here today, Larry, and Bob Jesse to look at the report and I want to thank those board members, but others who provided comments along the way and particularly all the members of the working group.

And so, with that in mind, I am going to ask Melissa Stern, who many of you have met, to provide us with presentation of what this looks like.

MS. STERN: Thank you, Gene. Hi, everyone. Thank you for having me.

I want to just underscore what Gene said, that this is, in fact, not very much new, but it is a compilation of the wisdom and the work that was being done through various committees and bringing it all together into a common framework. So, just a word on the process, the Strategic Planning Group, as Gene said, did work and come together to create a framework and then from that framework, the imperatives were actually sort of assigned or developed by relevant staff and committees who were most closely tied to that particular imperative and then brought back to the Strategic Planning Working Group who was looking at them for consistency, for linkages across the imperatives, as well as broader strategic lens and then interrelatedness. And so, that's the process.

The group met weekly over the period basically from the last board meeting until now. So, there was lots of active involvement of a working committee to bring this to this point.

What you'll see as an imperative and a description of the imperative in those strategic priorities that were determined to be the key supporting activities to help us arrive at that imperative. And so, we'll step through that and then save hopefully some time for how we're going to take what we have here to get it to the next level of deepness and richness that Gene was just mentioning.

So, do I have an ability to advance?

DR. DOUMA: You soon will.

MS. STERN: Thank you. One day, if Sherine has a Challenge Grant. So, there we are.

The materials that you have in the Board book are a little more extensive than what we're going to cover today. There is a letter that as we publicize, as we make public and post the Strategic Plan, the letter from Gene and Joe that will go

along with that. You have it to review it. It's not actually going to be presented today, but what we will focus is, as I said, on the imperatives and the strategic priorities that support those.

The vision and the mission you've seen before. We've been involved and worked over the last ten weeks to flesh out and refine the vision and the mission as something that was adopted by this board earlier in the year or last year. And so, again, we're looking at imperatives that are in support of these.

So, in the engaging patients and stakeholders, this is work that, as you would expect, we did in cooperation with the COEC, as well as the PCORI Engagement Team. And so, the imperative here says "Patients, caregivers, and other stakeholders participate meaningfully in the PCORI research enterprise from topic generation to final dissemination of research results." So, I think the key points here are the meaningfulness, the participation is meaningful, and then, of course, the longitudinality that we're talking all

the way at the beginning of topic generation and that this engagement carries us through to dissemination.

And so, then the priorities that we talk about in order to get us to our goal I think are how we first bring stakeholders and patients together with us and this is the inviting and valuing their wisdom and of course that we want them to represent a broad cross section of those stakeholders and this is where we also cover questions of access and disparities, that we want to make sure that we're eliminating barriers to participation so that those who participate with us that we will reach out and we'll make extra effort to make sure that people are able to participate together with PCORI.

The next is something we talked a lot about and exchanged a bit and it's about training and you were just talking about earlier with regard to the Methodology Report. Create a community of people who are training to do this work with us, and so, that includes actually patients and

caregivers and this was something that came out a lot in the deliberations of the working group, clinicians and researchers, as well. We can't assume that it's only the patients and the stakeholders that we need to train, but also clinicians and researchers need to be similarly trained to participate in this new fashion. And then there's something really nice that says "Collaboration is required in all stages of research," something I want to call out for you so that as we set out our funding announcements and as we set out our ways of operating that we are going to make an expectation of collaboration.

The next is I think something that some of us talked about last night at PDC with regard to prioritization, that we communicate transparently and regularly our approaches and our methods for prioritization for our decision-making and our funding and that in doing so, we create trust. And so, a part of the way we go about engaging patients and stakeholders.

And then, finally, to Gene's point, this

just ties to what you were talking about this morning, that there's going to be a learning, an ongoing feedback loop and a learning dynamic as part of this that we will continually evaluate and refine our processes so that we learn and incorporate those that work best and we continue towards our goal of a robust community of stakeholders and I think that's really important and that we're trying something new and we don't necessarily right now know the best way to do it, but we know we're starting and we need to study and learn from it and continue to evolve.

So, the next one is the advancing of rigorous PCOR methods. It follows nicely from the conversation that we just had and, again, we did work on this imperative as well as the priorities with the Methodology Committee, who are very busy, so, largely Sherine and Sharon-Lise and then they did solicit feedback from others. The imperative here comes directly from the Methodology Committee's blueprint. It says "PCORI methodologic knowledge and standards are adopted as best

practices across the nation," and, again, very tied to the conversation we just had. And so, the priorities here are things that we're engaged in and you've just discussed identifying the gaps and knowledge. So, what are the methods that we need to learn more about that we need to know about?

CHAIRMAN WASHINGTON: I'm sorry, Melissa. I'm going to ask you not to go through each one of these.

MS. STERN: Okay.

CHAIRMAN WASHINGTON: Because we just reviewed these in Methodology.

MS. STERN: Okay. So, I think that probably the important parts here are the enhancing the capacity of researchers to use these methods and that ties to the dissemination plan that you talked about. Thanks, Gene.

The conducting of PCOR, as you would expect it, fits with the work of the Program Development Committee and the imperative here is "PCORI will impact decision-making in practice and patient outcomes through a research agenda that is

uniquely responsive to patients and stakeholder input," and tying back to the priority and the imperative we just talked about under "Engaging Patients and Stakeholders," here, we say that we're going to engage patients and other stakeholders, again, in identifying, prioritizing, and conducting comparative effectiveness research, so those parts of the process, and then five bullets are really related to our research agenda. So, those are reframing just in action words of the research agenda.

The communicating and disseminating of PCOR findings, working here again through the COEC, as well as talking to the Dissemination Workgroup and the Engagement Team and the director of communications. Here, the imperative is that patients, caregivers, clinicians, and other decision-makers use PCOR to improve health care decisions, health care delivery, and health outcomes. And I think some important things here on the priorities so that I don't go line by line is that recognizing the role of AHRQ and their

important partnership, and so, working with them to create a framework that gets to PCOR-specific dissemination and that part of that, as Joe said, we're not disseminating just yet, but the creating of the "pull" right now so as research starts to come online, that there's people waiting for it and wanting it.

Next is about really making ourselves known as a trusted source and that people want the research that's coming from PCORI-funded researchers and that includes, again, tied to the conversation we just had, how we develop products out of these things and partnerships, and all of this in dissemination and communication, there's bidirectional channels of communication, and so, we need at this point to begin establishing those and those include all of the social media things that you can think, web-basing, the conversation we just had earlier about our web platforms, and so, taking a real active stance in developing those platforms that will be used both to engage stakeholders and then to help them receive and encourage their use

of the products.

And then here, too, we're talking about effectiveness and this is about the learning nature of PCORI's organization, that we will look at how successful we've been in building awareness and communicating with our audiences and understanding ultimately is uptake occurring? Do people use the work that's being produced by PCORI?

And then do we research, and this is tied back again to the conducting PCOR, but one of the things that we're going to research in conducting PCOR is dissemination practices and communication practices, and so, we're talking about making sure that that loop is closed there.

And then in development infrastructure, it doesn't fit as neatly in their single committee structure, so we worked with an ad hoc group of members of the PDC and the Methodology Committee, some of the same people who are working on the workshop in Stamford in July, and here, the imperative is promoting and facilitating the development of a sustainable infrastructure for

conducting PCOR. "Infrastructure" means many things, of course. And so, here, we're talking about those things that include data and how you expand and link and use data to conduct PCOR and especially to do it efficient and reproducible way. The methods that go along with that, so, this is something that is really important, that as we move to greater use of electronic research, what are the right methods for extracting them and making sense of those data, things that we just talked about, missing data, and how do you use methodological approaches to ensure validity in those challenging circumstances?

And then I think something that feels very PCORI in all of this is that as we participate in these efforts and talk with the myriad folks who are having these same conversations, that we have a specific role in making sure that patient interests are incorporated into the problem statement and as well as patients are being incorporated into the governance of these solutions. And then the third time that you'll see our desire to enhance the

capacity of researchers, and so, the training here that comes across many times, but I think is a big theme.

So, enhancing the capacity of researchers to conduct PCOR and then finally this is an infrastructure matter which took me a little bit to understand, but I'm sure you all understand, facilitating the use of PCOR results to improve outcomes. So, that's another piece of infrastructure that's quite different from data networks, but it's about how do you link in your infrastructure to people who will actually put what is done into practice?

So, before I get to the next step, shall I stop there, Gene?

CHAIRMAN WASHINGTON: Yes.

DR. NORQUIST: I have just a --

CHAIRMAN WASHINGTON: Please.

DR. NORQUIST: Yes, okay, Gray Norquist, member of the Board.

I seem to be being moved around to sit next to the speakers.

MS. STERN: [Inaudible.]

DR. NORQUIST: And I know I've been on the calls and have done this and maybe I've missed this, but there's a point I think I brought up before on the infrastructure. Like number four, where it says "Enhance the capacity," I would say enhance the capacity of researchers and stakeholders to conduct because we're leaving them -- I mean, there's this key issue about infrastructure where it's not just about making it possible for the researchers to do, we've got to build infrastructure that takes into consideration you're going to have to have communities and you have to participate in trials and that's a big deal that would really be different, and I'd just like to see that and we can't forget that aspect of it. I mean, I know you said it in some other ways and stuff, but it'd be nice to show.

CHAIRMAN WASHINGTON: That's a good point, key point.

Allen?

DR. DOUMA: Allen Douma, Board Member.

I need to jump ahead so I can reference back. When we talk about the future, it's really important the timelines and what you've set up is how to take the next step, which I think are really good. In that though, your reference how we are comparing things to our vision and that, to me, automatically I come back to the vision statement and I presume that's what our vision is, unless there's something else, and we actually haven't adopted the vision statement yet for our vision, so, we may want to talk about that a little bit.

And as you know, because of the e-mail I sent around last week, and because, for example, on page 8, the slide it says "Communicating and disseminating PCORI findings," it actually does use the term "use." I know it's bigger than patients and our vision is patient and public versus the discussion has do we use the term "use" versus "can use." I don't really care. What I care is that everybody agrees that the adoption utilization of information by stakeholders, patients, and all is one of the critical barriers that we have to deal

with, research on, and fight over. Having that in our vision statement, I think would be helpful. I use the term “use” and not the term “can use” because right now, there's information people can use. The problem is they're not using it often enough, effectively enough.

Now, in talking to Melissa yesterday, she said well, “can use” also could be a way of saying usable. Well, I think if that’s the statement we’re making, we ought to use that term “usable” so it’s not confused and/or our vision statement’s pretty short, we could put use and usable, information that is usable and used to make the statement both we want it to be good information and we want it to be used, and, in fact, later on, the argument, the pushback a little bit is are we being too paternalistic to say our vision is people are actually using information?

Well, we talk about later on that we are going to facilitate, update. A lot of our work is actually toward that end, and I don't think we’re paternalistic to want people to use information.

That's the end of my story.

CHAIRMAN WASHINGTON: And there is another part to the presentation --

UNIDENTIFIED SPEAKER: Mic.

CHAIRMAN WASHINGTON: -- that Allen and alluded to towards the end [off microphone].

UNIDENTIFIED SPEAKER: Mic. Mic.

CHAIRMAN WASHINGTON: -- imperative areas, as well as each one of the strategic priorities. I mean, for those of you who -- the staff know where we are, the Board members who are listening in, again, I emphasize this is really not "new work" per se, but what it is, it is highlighting some of the thinking that's taken place in some of the areas like relating to engaging patients and stakeholders by those working groups where there is no statute that require that we have a public comment period, but this is a way for everyone to know even at this early stage what is the thinking and what we see as the priorities, and, eventually, this document, in fact, immediately after this meeting, will be available online, and so, that it

will be an ongoing source of input from all of our stakeholders and partners as to what it is we're thinking in each of these respective areas.

You will note that on the section that deals with PCOR, and we're going to get to it later, this is conducting Patient-Centered Outcomes Research. Those five we didn't tinker with. They come specifically from what we've been discussing in public for the last year-and-a-half, and so, that's not new in any kind of way and while we're going to be voting on that later on. And for me, what the exercise has done besides the process, it is encouraged and/or forced in some cases us to be more explicit at this stage and to be a little bit more focused and articulate about what it is that we're thinking or the important undertakings in each of these other imperative areas. And so, it reflects the thinking that's guiding the discussion in the dissemination and communication in the infrastructure thinking section, and you already know about methodology.

And so, with that, I see three and then

we're going to go on with the additional presentation. So, Larry and then Harlan and then Kerry.

UNIDENTIFIED SPEAKER: [Off microphone.]

CHAIRMAN WASHINGTON: Okay.

DR. WEISMAN: I guess I had a question, Gene. You're stating this is going to go on the website, which it will, and it goes back to Allen's comment. This is sort of a mixture of things that we were doing already and we agreed to, like the mission statement. I forget when we locked it. We locked it.

CHAIRMAN WASHINGTON: Right.

DR. WEISMAN: And Allen pointed out that the vision statement is pretty good, but it's a recommendation, I guess, from that.

[Cellphone interruption.]

DR. WEISMAN: I'm sorry, I guess I'm getting --

UNIDENTIFIED SPEAKER: Somebody disagrees.

DR. WEISMAN: Yes.

[Laughter.]

DR. WEISMAN: It's one of stakeholders.

[Laughter.]

CHAIRMAN WASHINGTON: Are they telling you to be quiet or what?

DR. WEISMAN: Yes. Let me see if I can get back to my train of thought.

[Cellphone interruption.]

DR. WEISMAN: I'm sorry; I'm going to turn it off. It's off.

CHAIRMAN WASHINGTON: Harlan, you can take that.

DR. WEISMAN: No, no, it's turned off.

CHAIRMAN WASHINGTON: Okay.

DR. WEISMAN: The purpose now, and I think we have the strategic principles, many of which we're following and it's good for the public to know what our plan is, I guess it's two aspects that I had a question about, and one of them is probably in the second part. But when this goes up there, what are we going to do about something like the vision statement that's still a work in progress, and, in fact, I think there is the

additional idea that all of this is evolutionary. In other words, this is where we are on whatever day it is, May 21, 2012, but we anticipate that as a learning organization as we learn and grow and get feedback that we may modify this along the way, and I guess that would even include the vision and mission, but could you just comment on the vision and maybe the other elements about do these things get locked the same way the mission did?

CHAIRMAN WASHINGTON: Well, our thought is based -- I mean, you were part of that group though [off microphone] long-term is that there is a [off microphone] ideally this year when we have more detailing -- is this on?

When we have more detail, particularly as it relates to the strategic priorities that we will say we move beyond Preliminary Strategic Plan to this is the strategic plan as of today moving forward. We're not at that point now, and so, the objective today really is for us to present this in open forum and for the Board to continue the discussion about what's reflected now, but not

trying to wordsmith it and to comment on what's being planned over the next three months.

And so, specifically as it relates to the vision statement, no, we're not making a decision today that's finalized. Allen has made some comments, there will be other comments, but we're not going to say that this is the vision statement today.

Based on a longer-term plan, yes, the idea would be that we would -- and why don't we get to that in a minute, but we would say this is the strategic plan for PCORI that we're working with as of X date and it can be Version 1.0, for example. Right now, it will be labeled Preliminary Strategic Plan.

DR. WEISMAN: Okay. Please.

MR. BARNETT: Well, gee, I think that you just spoke to what I was going to say. I like what's here under the strategic priorities, I'm just having a little trouble understanding the full context of it, given the fact that it feels like as I read these that we're trying to cover the

waterfront, we're trying to say here's all of the stuff that we want to do as an organization, and the process of really creating a strategic is that process that you just alluded to of making choices. The fact is during any given quarter, during any given year, we're not going to be working on all of these things at once and we're going to have to make some choices as to which ones to move forward and which ones not to, and so, I really look forward to some of those discussions because, frankly, I think that's where the real heavy lifting of creating a strategic plan comes in.

CHAIRMAN WASHINGTON: I know that Rick and Harlan [off microphone] with Melissa, so --

DR. SELBY: As was Francis.

CHAIRMAN WASHINGTON: As was Francis, and so, that's one of the reasons why we are already planning to move in that direction, and so, a great segue to the next part of this presentation.

MS. STERN: It is. Yes, thank you. That's perfect. That's right, this is very broad and aspirational and then there are real choices

that need to be made and they need to be made, I think, if you take through this set of activities in the context of where we are right now, what our strengths are, what we have, and then what are the most important things we need to do? So, I think as Rick or Harlan or most people who have done strategic planning will tell you, that there's something really important about taking an assessment of our current state. Some people use SWOT analysis as a way to do that, but if we say that these are things we want to get to, where are we and what's the delta and then what choices do we make, but are those things that are most important to get us there and I think that is the work over the summer.

What we aspire to do between now and the next board meeting is to begin a deepening process that leads us to a strategic plan that guides the hard decisions, the hard decisions which is we're not going to do this right now or we're going to do this in a different way. And so, laid out that we would first be doing that current state analysis,

taking a look at it and seeing then as a result where imperatives may need to be revised.

There's something that -- I think Freda's not here, but she's pointed out in the past, which is we don't have a cross-cutting theme kind of way at looking at our strategic plan and often folks do, and I think as I talk, you see there are cross-cutting themes that are emerging that require being done cross-cutting to do them most efficiently and to gain the most leverage and we have to address those. And so, the conversation that keeps happening about a learning organization, how we build that, I think, might be one good example. So, taking that into a consideration and then really looking at that current state, where we are right now, what our ideal state is and the strategies that take into account our resources, our limitations, our time horizons, and those that will get us towards the vision.

And then I think something that you've all said in the past and that we as staff really value, as well, is the roadmap. That includes the

milestones, the accountabilities, and the metrics. And so, that the place where for at least us, as a staff, we're excited this is how we operationalize this and how we can hold ourselves to the strategic plan and to the expectations that you all have set out for us. And then as was also articulated, that this is an iterative process and the strategic plan would be updated and re-updated accordingly. It's a living document. And so, the idea would be to bring a strategic plan that has some of those hard choices, as well as roadmaps and milestones and accountabilities back to you in September.

CHAIRMAN WASHINGTON: We have Larry, he's already up, then we have Sharon and then Allen.

MR. BECKER: So, this is terrific work and this is Larry Becker on the Board, and begin to be able to put some real meat to the vision of what's about to happen. And it is probably an important second only to the outputs of what we envision happening. And to the extent that we begin to put this on paper, it seems to me that it also begins to answer the questions that we know the public are

beginning to ask. What are we going to do and when are we going to get this done? And I would hope that by the time we get back together again in September, we really do have that roadmap laid out with measures, with resources, with dollars so that it is really tangible so that everyone can really look at it and say this is where we're going to go, agree with it, change it, move it around, but it really can give us the roadmap and the thing that I think people are looking for now, we'll be 2-years-old at that point.

CHAIRMAN WASHINGTON: On one of the points you made about in terms of the output and what it's going to allow the public to understand, I want to emphasize that these deliberations that guide it significantly about what we've already heard from the public over the last 20 months. So, it's important to know that these priorities and eventually decisions that are going to be made regarding priorities are going to be greatly influenced by what we've heard and what we'll continue to hear going forward. And so, that's

another advantage of getting it out there.

MR. BECKER: Right.

CHAIRMAN WASHINGTON: So we can get even more focused feedback in some of these areas.

MR. BECKER: Right, and the public will know that they've been heard.

CHAIRMAN WASHINGTON: Been heard, that's right.

MR. BECKER: Yes.

DR. DOUMA: Now, I'm sure that all of us on the Board have been involved in strategic planning processes over and over again, and based on experience, we all recognize there are many different models or templates for a strategic plan, and I think it'd be helpful for the Board to be able to look at what's the template or model we are going to be looking at or following, i.e., what are the key elements in our strategic plan before the specifics of how we carry those elements out so it can come to that agreement and not have to have that discussion after we've done all this work up until September. And it's also important that we

look at -- and I already talked to a guy about it a little bit earlier -- is that a lot of the emphasis in the strategic plan are the programmatic side. We also have to have a strategic plan for the PCORI as an organization itself and perhaps the Board as an organization itself, as well.

CHAIRMAN WASHINGTON: Particularly those two latter two points, they're important because they're not incorporated here and that may very well be a separate one, but we do need to develop it and that's about governance in particular, and that's a very good point.

Sharon?

DR. LEVINE: It would be helpful, Melissa, for the Board and the committees and the Strategic Planning Workgroup to have a how map to go with this to understand what the expectations are for all participants so that we can begin planning our work to accommodate this in terms of deliverables and where we have input, where we have involvement.

MS. STERN: Absolutely. I think both points, there's work that I've been doing in the

background to prepare for this, should you all find this is the way we should go forward, and we can start sharing that quickly.

DR. LEVINE: For involvement or input?

MS. STERN: For both.

DR. LEVINE: Okay.

CHAIRMAN WASHINGTON: Yes, I would underscore that this is not a case where as a board we are saying this is our working plan, staff go forward. So, this is not a handoff. I want to be clear to everyone, this continues to be a collaborative effort. This is a framework for us to be working together, especially now that we dive more deeply in gathering information in order to make those difficult choices. And so, for those that are on the Board who thought that you were going to spend a whole summer at the beach, that's not the intent here.

[Laughter.]

CHAIRMAN WASHINGTON: And so, I'm glad you raised that question. I know that's not what Joe, Melissa, and the staff were expecting.

The roles that you play in your respective working groups and/or committees are still there. The big difference is now we have partners and help in the form of extremely capable and committed and devoted staff. Okay.

Well, any other comments? Melissa's group can see what's ahead, and, again, I want to thank all the Board members, particularly those of you who worked on the working group with us for helping to create this kind of clarity at this point about where we are, what we're doing, what we're thinking, as well as what we're planning over the next, what's that, four months, five months?

I will confess that I've told Joe and Melissa I thought that having this by September was a pretty ambitious timeline, but they wanted to stay with it, and so, far be it for me as a board chair to question their ability to deliver it, but this is a live broadcast, and so, we've been public in that we're going to deliver this kind of follow-up report in September. And so, thank you to Melissa and to all the other staff and board

members involved. Okay.

Steve, I'm going to ask you for reasons you understand to guide this next discussion and introduce it.

VICE CHAIRMAN LIPSTEIN: Thank you, Dr. Washington. So, for those of you who are listening on the webcast, this is Steve Lipstein. I'm going to moderate this next section and shortly I'm going to introduce Leah Hole-Curry to take us through this section, but if accepting the Methodology Committee Report and just endorsing kind of the direction of the strategic plan wasn't meaty enough on this early-morning agenda, what we're about to do now is review the genesis of the National Priorities and the Research Agenda and Leah is going to take us through the processes and the methodology that we have followed in receiving public comment, including them into this final draft, and to be explicit at the end of her presentation, we are going to be asking the Board to approve this Version 1.0 of the National Priorities and the Research Agenda.

So, Leah, you're on.

MS. HOLE-CURRY: Thank you. All right, well, now that we've covered the objectives for the National Priorities and Research Agenda, I can move to slide two. But before I do that, similar to what we've heard this morning, you won't have the inspiration that we received from our Methodology Committee, but we'll have to float based on that and Harlan Krumholz is the other board member that was assigned or tasked or volunteered with establishing or leading the Research Agenda, and he's not with us today, and he definitely brings the impassioned speeches to the committee. So, with that --

MS. HUNT: We've had those.

MS. HOLE-CURRY: And now we're going to get output. So, I want to thank you Harlan and then I also want to thank Arnie and Carolyn, who led the National Priorities discussion, and we actually through our continuous learning system evolved to have both of those come out together or in a finalized document that reflects both of

those.

So, at this point, we are going to be asking for a board vote at the end to accept this Version 1.0, and I noticed that it didn't get into the slides, but it was really important for me to underscore the fact that we are asking for final approval for this first version. So, it's final, but it's Version 1.0, recognizing that as we learn more, we anticipate coming back and analyzing whether this meets both our Strategic Plan and our statutory obligations that we've set out.

So, just a little bit of history because not only is it for the Board's reminder about where we started with this and the public, as well, we talked a little bit about this at our special meeting, so, I won't cover it in detail and you had detailed slides there, this process actually started at our first board meeting, you'll recall, where we all started discussing what we had to do first and next, but in terms of crystalizing around the criteria that we were going to start to use for National Priorities, that began basically in the

summer of 2011. So, we are nearly at a yearlong process for both the National Priorities and Research Agenda, where we have talked about this at the Board, started to refine criteria, embarked in many different analysis.

We've had many different presentations, we've had lots of staff involvement to help bring us materials so that we weren't reinventing the wheel and to distill down what our statute requires us to do, and that process is simply outlined here in terms of the criteria, the nine that were outlined by the law, the draft priorities that we came up and the corresponding agenda.

We've had various public comment at each phase, but we also had our formalized public comment period and then we analyzed that in March of this year and at our April board meeting, what we asked for was approval conceptually based on the feedback that we had received, go ahead and incorporate that into a final document to bring to you in a specific way. So, we'll revisit what that was and we did get that approval from the Board to

go ahead and incorporate the feedback in a way that we recommended and to bring to you now this final vote of the first version of our National Priorities and Research Agenda.

So, once again, thank you for all that work. If you guys will remember that balloon slide that went into a little arrow from one our very initial drafts, that was revisiting that. I thought that was quite humorous.

So, aside from being mandated in the legislation, the two things that we want to cover is this becomes a preliminary roadmap for PCORI research activities and it's a living document. I think we've already been over that. So, it becomes also a mechanism for us to gather feedback and to benchmark ourselves against how we're doing and whether that's truly meeting our strategic objectives.

All right, so, moving into specifically the stakeholder feedback, way back a year ago, we did receive feedback on not reinventing the wheel. As early as February of 2011, we were looking at

the National Quality Strategy, National Priorities Partnership, which was outlined in our statute, as well as IOM, the Federal Coordinating Council, NCER, National Prevention Council, and, oh, I mentioned the National Quality Forum, to look at how they had started to set priorities at a national level and what we should learn from that given our unique mission and vision. We also conducted that environmental scan to really dig into what those frameworks that they utilized where and identified how we could fit that into the criteria that we had been given. And that framework became the underpinning for us in terms of both the priorities and the Research Agenda.

While we've taken comment throughout, we also had a formal public comment period, which is mandated by our statute and the additional forums that we held to really ensure that we were gathering appropriate feedback for this very foundational document for us. Through our formal public comment period, we received almost 500 public comments. Those will be posted. We also

had numerous stakeholder and patient dialogues, including a national forum. We had focus groups and interviews that we conducted and individual meetings.

So, next, we're going to talk a little bit about what we did with all of that feedback to make sure people can kind of see themselves in where it was. We did ask staff to have an algorithm to help us identify key terminology so that we could aggregate comments into themes and analyze how that impacted the proposed public priorities and research agenda.

And we had different individuals take the computer algorithm and essentially validate that to review it and analyze it to see if they were inappropriate themes or if we had missed something and then we aggregated that and our staff first came back to us with quite a few themes and we asked the impossible of them, to aggregate that up a little bit further into a set of maybe 10 to 20 key themes and they came up with 15 and then those were reviewed. And then the Program Development

Committee reviewed in detail in several face-to-face meetings, as well as some key individuals all of the comments and then these themes and decided on recommendations about how we would approach the response to those themes. And that's what you heard on the April call that we asked permission of. These are the themes we're seeing and here's how we would like to see them incorporated and could we have permission to go ahead and do that incorporation and produce a document for you to review.

So, this was the discussion that we had in April and the request that we had of you, was to decide on the response approach and get permission to go ahead and incorporate what we thought was more appropriate into the document to present to you and that was approved in April to go ahead and do that. So, staff and the PDC have moved forward and done that. So, you have in your board materials the proposed Version 1.0 final National Priorities and Research Agenda. And what I'd like to spend some time walking through is these 15

1 themes and what we chose in terms of a response
2 approach.
3 So, moving back, the response approaches
4 that we kind of categorized it in, is should we
5 change language within the National Priorities and
6 Research Agenda itself related to this theme?
7 Should we embed it into PCORI operations and
8 processes? We got lots of comments about how we
9 should conduct the PFA itself and those are very
10 helpful and important comments, but they might not
11 be incorporated into the Research Agenda, for
12 instance, itself. Address it in the summary
13 document that provides the context and overview to
14 ensure that we're providing an appropriate level
15 setting for what we intend to accomplish in the
16 National Priorities and the Research Agenda itself.
17 And then future consideration. This is
18 not something we choose to adopt now, but it is
19 something that we would consider in the future.
20 So, those were kind of the options that we chose
21 for these 15 themes.
22 What I'd like to say overall is that out

of the 15 themes, 11 of the comment themes resulted in changes in the summary document itself to incorporate the fact that we agreed and acknowledged these comments and felt that our National Priorities or Research Agenda or the mechanism by which we would implement these would incorporate that feedback. Eight of these themes, eight of the fifteen, so, more than half actually resulted in changes to the National Priorities and the Research Agenda. And then four of them, we did not make the changes that were generally identified in them.

So, I'd like to talk about those as groups and emphasize the robust discussion that occurred around those. But I think we have gone over each of these themes in detail and in your appendixes, you have a more explicit description for this PowerPoint of those key themes and then an explicit response too, and that's part of what framed the summary document and the changed language.

DR. WEISMAN: I have a question, just a quick clarification.

MS. HOLE-CURRY: Absolutely.

DR. WEISMAN: I wondered when I looked at the slides in advance whether the order is implying something in terms of quantitatively what we got as feedback?

MS. HOLE-CURRY: So, the question is in terms of the order of the themes, does it imply something about the theme itself? And, no, these themes were put into this order just randomly. We could have grouped them and we did give you some more detail as we kind of gathered permission to approach this, but we didn't do that for these. So, from the April presentation, you can go back and see those groupings in a little bit more detail. But I am going to focus on especially the ones where no changes were considered appropriate because I think that's a core component where we have an obligation to discuss and understand it as a board before we finalize this document, that there are many that we incorporated and there are some that we did not.

So, around the four that we did not make

changes, the first one and one that garnered a lot of discussion and debate actually going back to, again, one of our very, very early meetings, I pulled up our September slides, where we talked about previous priorities, have various levels of granularity and one of the themes that we heard relates to this granularity in that it requested that we reorganize our research agenda and potentially our National Priorities under conditions or diseases specifically. That is one type of granularity. There's another type of granularity that would continue to focus not necessarily on conditions or diseases, but also get more specific in terms of the types of studies that we wanted to see.

So, I'd like to talk about that one first and go back. I think when we had discussed this and I think this is what got the most committee discussion and it's taken up the most board discussion, frankly, we've gone back and forth about the most appropriate approach and the level setting that you heard from the Methodology

Committee as well as our Strategic Plan forms the basis of why as a board I think conceptually we did not agree to make this change and go to condition-specific.

The one thing that I will point out is that we are not foreclosing the opportunity to have specific calls for research in areas that we identify a gap and that could be very granular about a particular application that's patient-centered or a particular disease or indication or condition or innovation. So, it doesn't foreclose that opportunity. In fact, it leaves it open for that, but we're not going to specify those.

And there are some reasons why. I think significant from Sherine's discussion this morning; all of us are here not because research isn't occurring on a very robust level in the U.S. and around the world. There is more health information and more choices today than ever before and that should be celebrated, but we have a unique mission and that's to recognize the patient voice and the one thing that I pulled out of all of the patient

sessions that we went to was one in New Orleans, and a particular individual said if you want to make a difference to me, you need to come walk in my shoes. She didn't say hear this specific disease, I have this condition, and I think that that was fundamental for me.

But the lack of connection that we have between the research world and the practice world and the patient world is really what we're here to solve and starting with a Research Agenda and National Priorities that segments people based on a biological condition does not enhance that connection. So, I fundamentally believe we're on the right path, but I believe also as a learning organization that we have to benchmark ourselves against that in setting a Research Agenda and National Priorities that are not specific to condition or disease or specific in another type of granular way at this point.

I think those compelling stories about the lack of connection is really what we're here to focus on and what we've tried to do with this first

set of priorities, and I'm really proud of that effort. So, I think it's something to be celebrated, but it doesn't mean that individuals didn't have appropriate concerns that this is a different way of managing research and we need to be mindful of that and ensure that we're addressing any gaps that it creates by doing it in a different way.

So, again, there was additional language added to the summary document to express this context and it doesn't foreclose the opportunity for a specific cause that are more granular in nature.

So, moving onto the next area where there was no change, there was a theme about ensuring that we had health IT infrastructure, networks, and tools and that we were really focusing on those. The reason that there was no change made to the Research Agenda and National Priorities related to this is not because we don't agree that this is very critical and important as we've heard discussion today, but that the research agenda is

focused on research about these things, and to that extent, we think Priority 5 already incorporates the extent to which we might fund research about health IT tools or patient data in terms of both methods and infrastructure. But in terms of other investments in infrastructure, those are a separate conversation that isn't the Research Agenda if we should choose to do that. And so, that's why no change was made to that one.

On the next slide, you have a discussion about international models and the comment was that there are a lot of international models or the theme and that we shouldn't exclude those. We didn't make any changes because in terms of our research agenda, it's agnostic to the model that you might choose or the system that you might be doing your research within. So, we didn't really think that the comment was applicable and there isn't anything exclusionary in our National Priorities or Research Agenda that would preclude someone from comparing a model as long as it has a patient-centered approach and otherwise met the

criteria that we've established.

And then the final one where no change was made was regarding novel methods and I did want to spend just a little bit of time on this one, as well, in terms of explaining why no change was made here.

So, the first idea or concept that PCORI should be exploring innovative methods that focus both on the patients and innovative methods to accomplish the type of research that we want to have is embedded in all of our documentation, but the concept that we would move away from rigorous scientific methods to do so was not one that we chose to adopt and we wanted to make that really clear. If there's an exploration for how to do something better and it can meet rigorous scientific methods as established by our Methodology Committee or propose and alternate way to explore, we're very open to that, but simply saying we need to go out and generate information that's not rigorously-based is not where PCORI wants to focus. And so, we really wanted to ensure

that we do support and approach new methods that are going to support scientific and rigorous validated information. But those wouldn't necessarily include all methods of either communicating or being patient-centered.

So, those are the four areas where no changes were made and really the theme that was reviewed we didn't think was appropriate for adoption. The other ones were adopted in some way, although, as I said, only eight of them reflected in the document itself and then 11 of them are reflected in the summary document to ensure that yes, we believe we're acting consistently with what you've requested.

So, for instance, one of them was partner with organizations and stakeholders. It's not something that we felt needed to be in the National Priorities or the Research Agenda itself, it's part of an operational process that is clearly an important goal that we share and that we need to operationalize. And so, the summary document talks a little bit about that.

So, I think with that, I'll turn it over to questions.

VICE CHAIRMAN LIPSTEIN: Before we open it up to questions, Leah, since this has been a lengthy process, would you be willing to offer up the motion for approval of the Research Agenda and National Priorities Version 1.0?

MS. HOLE-CURRY: I move that we vote to approve the Version 1.0 National Priorities and Research Agenda.

[Chorus of seconds.]

DR. SELBY: Friendly amendment.

VICE CHAIRMAN LIPSTEIN: Do you want a friendly amendment?

DR. SELBY: Yes.

VICE CHAIRMAN LIPSTEIN: Go ahead.

DR. SELBY: So, I'm not an English major or a legislator, but the language says that we need to adopt them. So, I just --

MS. HOLE-CURRY: Adopt. Yes.

DR. SELBY: So, change the word from approved to adopt.

VICE CHAIRMAN LIPSTEIN: Adopt. So, there's been a motion --

VICE CHAIRMAN LIPSTEIN: Is there a second?

DR. KUNTZ: Second.

VICE CHAIRMAN LIPSTEIN: So, Rick Kuntz is the second. And before we open it up for discussion, I want to make sure I get in some really important thank yous. Not only a thank you to Harlan and Leah and Arnie and Carolyn for their leadership of this activity, but a thank you to all the Board members. You have been involved in this process of setting priorities and crafting this agenda, as Leah pointed out, from our very, very first meeting. This also represents PCORI's first and maybe largest significant effort to get broad-based input from a variety of stakeholders.

So, for all of you stakeholders that are here in the room and listening on the web, we thank you for all of your many comments and suggestions, and as Leah has articulated, many of those have found their way into this Version 1.0 and then,

obviously, just a special acknowledgement of the Program Development Committee under Dr. Kuntz's leadership, who put hours and hours of time and effort into making sure this process culminated in the recommendation that's before you today.

So, we have a motion, we have a second. Let me open it up for discussion.

Dr. Weisman?

DR. WEISMAN: Leah, thanks very much, and, again, I reinforce what Steve just said about all the work that's gone into it. It's very impressive.

I'm totally supportive of 1.0. In terms of this slide, the one that's right up there now on the overview of the themes and then in our appendix or specific statements, I think it's a lot of people took the time to provide us with feedback and my impression is although I may be wrong, and I think you indicated that, number one, specificity in condition and disease area is probably the most contentious and the greatest cause of discussion, debate. And while everything you said about it I

agree with personally, I think it's really important and we owe it to our stakeholders to really make sure that they know that we heard them, that we listened to them, and I'm afraid that by the terseness of our response to specificity either on the slides or the appendix slides we may say we know what you said, but we're going our own way, and that's not intended, I know that's not intended.

And, also, I would supplement and we've said at the last board meeting, Joe says it in public forums that you're at, that there is a plan for the Board to formally look at getting to greater specificity in some fashion and we've even indicated a timeline, if you will, for doing that, and that was sort of missing in this presentation --

VICE CHAIRMAN LIPSTEIN: Harlan, let me comment on this because it's really important. While it may appear terse in the context of this brief presentation at a board meeting, members of the Board and Dr. Selby in particular had lengthy

discussions with many of the organizations that offer these comments to assure them that their voices were heard and that we will be communicating in response and going forward.

DR. WEISMAN: Look, all I'm saying is that there's a lot of sensitivity about these things, Steve.

VICE CHAIRMAN LIPSTEIN: I understand.

DR. WEISMAN: And just talking to people, there's what we say and there's a difference sometimes between what we say and what people hear. And I think it's you almost have to continually reinforce the message in a way that people feel -- it's a trust thing.

VICE CHAIRMAN LIPSTEIN: Right.

DR. WEISMAN: And we don't have that much of a track record yet and I'm only suggesting that particularly on this one, perhaps some of the other ones, is that we really did hear, we really did take it seriously and this is 1.0, this is it for now, this is where we are, this is our first PFAs, but as we move forward, we actually have a plan to

look at number one, and I know we've said that a lot of times. I started out by saying that. There's still a lot of sensitivity about this issue and that's the only point I'm making is that when you get feedback from somebody, whether it's personal feedback or organizational feedback, it's really important that people feel your gratitude and they've been heard. That's all.

VICE CHAIRMAN LIPSTEIN: Got it.

MS. HOLE-CURRY: I just had --

VICE CHAIRMAN LIPSTEIN: Well, let's go with Michael, then Bob, then Ellen.

MS. HOLE-CURRY: I just had one feedback to that. If you don't think we've made that clear in the summary document because I think that's where we tried to articulate that in the living document form, not just necessarily in this PowerPoint, I think that's open to continued modification even though it'll be published. So, feedback on that's appreciated.

DR. SELBY: Just one little clarification. You'll notice on this table that Rick says no

change for number one. You'll also notice under "Response," that, in fact, we did make a change. So, this is a little bit misleading. We didn't change position, but a substantial amount of additional language was added to the agenda itself to account for those responses. The other last thing to just say is that this was the item with the largest number of comments, but they didn't all go in any single direction. They went in multiple directions. You should study this, you should study that so that, in a way, it almost helped to make our point that we didn't want to zero in on a handful of conditions on day one.

VICE CHAIRMAN LIPSTEIN: Michael?

DR. LAUER: Mike Lauer representing NIH.

I just wanted to echo that, that it is very important that we are going to be addressing this because the public is going to be watching. There was an interesting article that appeared in *PLOS Medicine* a week or two ago in which some people did a portfolio theory analysis of NIH-funded projects and looked at what specific topics

were being funded, how that relates to disease burden, and then tried to read in some interpretation about how we're approaching our own strategic planning. So, and there were a lot of problems with the paper, but the authors did make a very important point, which is that ideally, this kind of prioritization should follow some kind of objective or semi-objective analytical approach.

And I think that's something we can agree with, although exactly what that would be does require some work. And what we don't want to be accused of as time goes on going on down the line is that it just happened, that it just happened that we funded this many cancer project and it just happened that we funded these many arthritis projects, but rather that there was some kind of prospective analytic approach.

VICE CHAIRMAN LIPSTEIN: Got it.

Bob?

DR. ZWOLAK: Very briefly, because my comments mirror the ones that have just been made by fact that we have done little in terms of

disease or disorder-specific prioritization over now our two years of existence. Our inaction is, I think, starting to speak more loudly and this I see as a topic which is going to be very challenging by analytic method or whatever for us to set priorities. So, I do think and I fully support adoption of the priorities, I do think that yes, we're not foreclosing, but it's important that we engage in the process soon to decide if and what we're going to prioritize.

VICE CHAIRMAN LIPSTEIN: Ellen?

DR. SIGAL: Ellen Sigal, board.

So, I agree. I was one of the big proponents for disease specificity because patients do get disease, but I don't think we're ruling it out at all and I think that we are agnostic, we want to help patients and that doesn't mean we won't be studying specific conditions. So, I think for a starting point, this is where we should be. It's taken me a long time to get there, but I'm perfectly happy and I do know that we will start to study specific conditions that are important to

patients. So, I just wanted to put that for the record.

VICE CHAIRMAN LIPSTEIN: Thanks.

Dr. Norquist?

DR. NORQUIST: Yes, that's good because I would agree with Ellen. First off, we don't preclude anybody who wants to come in for a specific condition theoretically on these PFAs, so, they could do that. It's just that we haven't singled out any particular thing. The other thing is we're going to have to spend some time -- I've said this -- on the PFAs and others, what is our unique role compared to what -- the billions at NIH has, other have to fund this. I mean, we don't we want to be duplicating. So, we have a fiduciary responsibility to decide if we are going to be specific, what exactly in what specific areas compared to whatever NIH and others are going to do. So, that's another thing I would say.

On some comments, one thing I just want to be very clear about is that you're saying that we are approving this document that's after the blue

page. It doesn't have a 1.0 on it, but it looks like that it's right, that's what we're approving.

All right, so, a couple of just items in there. One is wouldn't change this, but there's a lot of overlap in some of the specific kind of recommended research stuff, but that's okay, it's good to have overlap.

The only other thing, I know we're going to talk about the PFAs and I looked at all the PFAs, but I didn't have this in front of me. I hope that each one of the PFAs that we're going to talk about later have every one of these somehow addressed in them.

And then I'll open up the ultimate can of worms, which is going to draw Joe up, but there's this table on page 20 which says how we allocate our funds and we never had any kind of transparent discussion about how we decided to put 10 percent, 40 percent. So, Leah, could you talk about that, about how that came about for us?

MS. HOLE-CURRY: You said you were going to drive Joe crazy, not me.

[Laughter.]

DR. NORQUIST: Well, I figured I'd pick on you first and then let Joe go. I need two people --

MS. HOLE-CURRY: All right, so, what you're talking about is the funding model. I guess what I would say is --

DR. NORQUIST: And I'm bringing that up because you're asking us to approve, and when we approve, we technically approve this.

VICE CHAIRMAN LIPSTEIN: Well, you're approving approximatelies okay, and there are several approximatelies. So, there's nothing hard and fast about this allocation --

DR. NORQUIST: Yes, but there's a big difference between approximately 40 and approximately 10 to the same public --

VICE CHAIRMAN LIPSTEIN: That's correct.

DR. NORQUIST: That's what I'm saying. You know what I mean? I'll take your --

VICE CHAIRMAN LIPSTEIN: Right. That's correct.

So, Dr. Selby, do you want to respond to that approximatelies?

MS. HOLE-CURRY: I just want to note that they were a subject for us to gather public comment on and they were in our draft versions and discussed here as part of the draft versions. I don't disagree with you, Gray, that aside from introducing them as part of the draft and getting feedback on, we haven't had a meaty discussion at the Board on that particular allocation. But I just want to be clear that it's not that this is new and we did discuss it here in terms of is this an approach we could live with and then we put it in the drafts that went out for public comment and actually asked for public comment on that as well as the priorities and the agenda itself. So, I just want to be clear that --

VICE CHAIRMAN LIPSTEIN: Joe, do you want to add to that?

DR. SELBY: Only a couple things. To echo what Leah said, this has been before us repeatedly and it does reflect discussions that have been had

in various settings. So, it's nothing new. We did ask for public comment. We found we got respondents who favored putting the bulk of the money in each one of the priorities.

On average, I don't think that's a good way to do it, given the wide disparities. On average, the pattern that we proposed held up across all people who weighed in, although it did tend to pull things together a little bit. That's, I think, predictable. If you put somebody out at 40, like we did priority number one, it's kind of predictable that it's going to spark comments particularly from people who want to pull it the other way. But the pattern persisted and that's the way the PFAs read now, too, approximately.

VICE CHAIRMAN LIPSTEIN: Gray, do you have a follow-up?

DR. NORQUIST: But my question is: Where is the rationale for choosing 40 over 10? I mean, that's just documented. And you've done a very good job of documenting this in our response and I'm sure some people said spend 100 percent in my

area or whatever, but we chose these approximate ones and I just think we need to be able to say what our rationale is, that we just didn't pick it out of the air and decide to do it. I told you earlier, Joe and I had this conversation that you can make an argument for 40 percent on CER because it's very expensive to do those kinds of trials, you could make an argument and comparison, but you need some --

VICE CHAIRMAN LIPSTEIN: So, Joe rather than craft the rationale on the fly here since it's already gotten great -- let's refer this back to the PDC Committee to help draft that rationale and we'll put it on further discussion at a subsequent meeting.

Sharon?

DR. LEVINE: Sharon Levine, Board of Governors.

My memory may be faulty, but I thought we had an agreement to not put this in. We had a board agreement to take this allocation out. Now --

VICE CHAIRMAN LIPSTEIN: Arnie, do you have a comment on that one?

DR. EPSTEIN: I sort of do. I vaguely remember this from maybe roughly around two board meetings ago, Steve. You broke us up into working groups and one of the things we did in those working groups is we focused on what the priorities were. I think there were a set of numbers that may have been generated by Harlan as sort of a straw man and we compared the groups individually to that and, as you might expect, the concordance was left imperfect. If I'm not remembering this correctly, I apologize to everybody.

There was also a question of what people meant when they talked about communication and dissemination research at a certain percentage because recall that we are getting roughly 20 percent going off the top of the PCORI allocation, already going to dissemination in infrastructure. And so, that got raised, but not engaged, and if I was going to put all this together, it's to say that this is a really important set of decisions

and is there any interest in reflecting further on these before we close on these right now because we have a lot of other stuff that we can close it on.

VICE CHAIRMAN LIPSTEIN: Well, hold on for a second. As a matter of process, we can label these are “preliminary” in our national priorities and in our Research Agenda, but it does give guidance to how we’re crafting the PFAs. And so, it’s really important that this is the preliminary guidance we are giving to the PFAs. If it turns out that we want to modify that, we can always change our minds, but this is a starting spot, it’s not an ending spot, it’s a starting spot.

And so, because we’re going forward with the PFAs and we’re going to hear about those extensively this afternoon, I would ask that we keep this as a starting spot for allocation and it would be subject to modification just like the priorities and the Research Agenda are subject to future versions, but we need a place to get started and I think, Sharon, that’s why even though we haven't had that meaty deliberative process around

this allocation, we wanted a place to get started with the PFAs so that we had some sense of how we were sizing the different funding announcements.

DR. WEISMAN: I think page 19 gives us that, the bottom, funding models, it sort of gives that escape clause that you're referring to, where it says that this is what we're thinking, but that the ultimate distribution is going to depend on what we see in terms of the quality of the submissions and as the research agenda evolves and it also says that there's overlap among these. So, I think this sort of gives us what you just said.

VICE CHAIRMAN LIPSTEIN: Dr. Douma and Dr. Zwolak and then I'd like to call the question, given the hour, if I could. So, Allen?

DR. DOUMA: Two questions. First of all, when we talk about communication, dissemination, and research, that 10 percent and that's above and beyond the AHRQ activities. That's only for the research in dissemination, it's not dissemination itself.

VICE CHAIRMAN LIPSTEIN: Correct.

DR. DOUMA: And so, and we haven't really budgeted that yet at all and whether we're going to have anything in this budget -- by default, we'll have staff working on it, but we need to start budgeting what's the additional amount of money we're going to put in to actually disseminating the research that we do.

VICE CHAIRMAN LIPSTEIN: We do have a placeholder in the current budget, but given that we haven't funded the research yet --

DR. DOUMA: Right.

VICE CHAIRMAN LIPSTEIN: It'll be in subsequent versions of the budget that your committee's developing.

DR. DOUMA: We'll talk about that.

VICE CHAIRMAN LIPSTEIN: Right.

Dr. Zwolak --

DR. DOUMA: The second thing is --

VICE CHAIRMAN LIPSTEIN: Oh.

DR. DOUMA: Joe, as we've talked about, do we actually have the numbers that we got from that survey, the feedback of --

DR. SELBY: Yes.

DR. DOUMA: That would informative, I think, if we could see those at some point.

DR. SELBY: It's in the Summary Report and it's pretty much as I described it a minute or two ago.

DR. DOUMA: Which report is the Summary Report?

DR. SELBY: The Summary Report accompanies the actual priorities and agenda document. It's a summary of the public comment.

DR. DOUMA: Where can somebody access that?

MS. HOLE-CURRY: It was distributed to the Board, but it's not published yet because we're here having the conversation about it now. It's the context document for the National Priorities and the Research Agenda.

DR. DOUMA: And that was distributed?

MS. HOLE-CURRY: Right. And then --

DR. DOUMA: It didn't get out to Oregon.

[Laughter.]

UNIDENTIFIED SPEAKER: It's a long way.

UNIDENTIFIED SPEAKER: It's too far.

MS. HOLE-CURRY: The other piece is that all of the public comments were accessible to all the Board members along with the analytics tool about that. So, that's been available for close to a month now.

VICE CHAIRMAN LIPSTEIN: Dr. Zwolak?

DR. ZWOLAK: As a bit of formality, this document page 5 talks about a special public webinar that we held. I think that was noticed as a public meeting and I don't know if the term "webinar" actually includes meeting, but maybe it should say meeting and also I think potentially we need some minutes of that meeting.

VICE CHAIRMAN LIPSTEIN: So noted. Okay, Dr. Epstein, do you have something you needed to say before we take a vote?

DR. EPSTEIN: I'll take 10 seconds.

VICE CHAIRMAN LIPSTEIN: Go.

DR. EPSTEIN: Your procedural advice is very helpful. I agree with you that we need a

place to start and this seems like a good one, and I just wonder whether there's some way to move ahead in that frame, but also say that we will review this in a more deliberated matter subsequently.

VICE CHAIRMAN LIPSTEIN: That would be terrific. So, we have a motion to adopt, Version 1.0 of the National Priorities and the Research Agenda, including a preliminary allocation of funding, which we will spend more time discussing when we reconvene in September. It's been moved and seconded. All in favor?

[Chorus of ayes.]

VICE CHAIRMAN LIPSTEIN: Any opposed?

[No response.]

VICE CHAIRMAN LIPSTEIN: Any abstentions?

[No response.]

VICE CHAIRMAN LIPSTEIN: Okay. Congratulations. Congratulations to the Board, congratulations to the staff, congratulations to the stakeholders. Big, big milestone, big, big achievement. Thank you. Gene --

MS. HOLE-CURRY: I take that comment seriously, that what was missing from the presentation is next steps about that. So, I think that is probably a PDC, as well as staff shared task.

VICE CHAIRMAN LIPSTEIN: So, Gene is nice part of our Chair, Vice Chair team, and I'm the not nice part. So, I'm telling you that you have 25 minutes to eat lunch. We need to be back here at 12:45.

UNIDENTIFIED SPEAKER: I'm sorry, we eat lunch outside.

VICE CHAIRMAN LIPSTEIN: We eat lunch in the room next door, where we had breakfast.

UNIDENTIFIED SPEAKER: Okay.

VICE CHAIRMAN LIPSTEIN: Is that correct, Anne?

DR. BEAL: Yes.

VICE CHAIRMAN LIPSTEIN: Where we had lunch. But, really, in order to be fair to our public commenters and to the people listening on the web, you got to eat quickly, okay? So, 12:45,

we're reconvening after lunch. Thank you, all, very, very much.

[Whereupon, at 12:19 p.m., a luncheon recess was taken.]

A F T E R N O O N S E S S I O N

[12:53 PM]

CHAIRMAN WASHINGTON: Welcome back to this afternoon's session of the Board of Governors' Meeting for the Patient-Centered Outcomes Research Institute and in this next segment of our board meeting, today Dr. Selby's going to introduce the topic under the broad PCORI imperative of conducting Patient-Centered Outcomes Research of the Patient-Centered Outcomes Research Program Announcements. So, Joe, what we're calling PFAs, PCORI Funding Opportunity Announcements.

DR. SELBY: Announcements, that's right. Thank you, Gene. And let's just see. I'm not sure that these slides are quite working. I'd like to get to the first slide for the funding announcements presentation. Okay, good, that's good now.

See if I -- I can now, so, that's good. Okay, thanks.

So, that's right, we're going to spend the next, what do I have, Gene, 45 minutes?

CHAIRMAN WASHINGTON: Thirty.

DR. SELBY: About thirty minutes, just a little bit less, giving you a bit of the history of the development of these first funding announcements, PCORI Funding Announcements or PFAs and I should say the first funding announcements for what the legislation calls primary research, that is Patient-Centered Outcomes Research. We have heard this morning about the Pilot Projects which were methodologic in nature. I wanted to just describe for you briefly the process that we've gone through, particularly the linkage of this process with that of both the development of the National Priorities in Research Agenda and also the Methodology Reports' appearance on the scene development evolution and availability to us beginning on the 10th.

I want to pay special attention for the Board members, too, what we consider unique might be a slightly strong word, but the special features of PCORI research because we do feel that in some ways this helps to make PCORI research specific,

harking back to our conversation from this morning, and then I'm going to very briefly in one slide each describe the research areas of interest that are in each of four PCORI Funding Announcements and then I'm going to turn it over to Martin Dueñas, who will take you through our proposal for reviewing what we anticipate to be a very large number of responses to these four announcements.

So, as Leah laid out just a while ago, we have had a process of developing the National Priorities in the Research Agenda and that had to happen and we had to not only post it for public comment on January 23rd, close the public comment period on March 15th and begin analysis of the comments we received, vote on the summarization of the public comments that we received on our public webinar meeting on April 25th and then incorporate and craft actually those recommendations into changed language. All of that happened this morning as we began working on drafting these first four PCORI Funding Announcements, we were listening intently to these conversations and language from

the evolving Research Agenda, National Priorities made its way into the Funding Announcements. So, today, we're going to present these Funding Announcements to you, you've seen drafts at earlier points in time, and in a minute, I will thank the Board members who particularly participated in preparing these announcements.

So, we had writing groups, each of four Funding Announcements had a writing group and we've been working since just after the Baltimore meeting. So, board members sat on each of the writing groups and they lent not only representation of the Board strategic interest, but they also almost to a person brought content expertise to help us refine the way we talked about the research area, the gaps, and what we call exemplar questions, and I'll get more into those exemplar questions in a minute, too.

PCORI scientists and staff took the lead in putting these Funding Announcements together. There was one PCORI scientist responsible for each of the four and they worked with the team. They

brought content expertise, they helped refine the background section of the Funding Announcements, and they lent some exemplar questions to the announcements. We also contracted with scientists Avalere on the one hand and a scientist at the Palo Alto Medical Foundation, Dominick Frosch on the other, and they were charged with basically writing the initial literature survey that helped us then covert -- we converted into a briefer background segment of each announcement. They helped to highlight evidence gaps that we call out in the announcements and they also provided exemplar questions.

On each team, we had an advisor from the NIH and an advisor for AHRQ who brought both content expertise and awareness of what else was funded and with a particular focus on what was going on at NIH and AHRQ in these areas. So, we were able to help us steer clear of large funding efforts already underway. We don't want to be redundant in these efforts.

These are the Board members, so, and this

slide also introduces you to the titles of the Funding Announcements, and not surprisingly, these are the same as the first four priorities in the five national priorities. The fifth priority, which is related to infrastructure and accelerating PCOR has been postponed a bit because there's some greater complexity to it, we want to wait for our workshop on the Electronic Health Record data infrastructure, and those will appear at a later point sometime this summer, one or two announcements under Priority Five, but the first under "Assessing prevention diagnosis and treatment options," Harlan Krumholz, Ellen Siegel, and Harlan Weisman all participated in the meetings and lent great comments throughout the process, including reading and editing the drafts.

The second priority and the second Funding Announcement is improving health care systems, and Arnie Epstein, Christine Goertz, and Leah Hole-Curry participated in those calls, read the drafts, and contributed language, editing, and lots of suggestions. And under "Communications and

dissemination research," Allen Douma, Gray Norquist, and Sharon Levine participated in those meetings, read the drafts, and contributed comments, and under "Addressing disparities," Debra Barksdale and Carolyn Clancy did the same. So, we really want to thank all of you. It was a fabulous example of tapping the expertise on the Board and also making sure that board perspectives were represented as the staff evolved these announcements.

So, the announcements come straight from the agenda and we like to think that we have created materials, the Funding Announcements and the application guidelines that are quite user-friendly and that guide the applicants to respond in a way that is consistent with PCORI's particular priorities and interests. There's two different documents. There's actually four of one type of document. There are four Funding Announcements and these introduce the four topical areas, and then there is one set of application guidelines and these application guidelines serve applicants no

matter which of the four announcements they're responding to. All of this is online, and so, you look at the Funding Announcement and if you're interested after reading the Funding Announcement, you just hit a link and you go straight to the application guidelines.

So, in the application guidelines, we present these special features of PCORI research. We have a very clear statement that PCORI-funded research will always engage patients and other relevant stakeholders in every aspect of the research. So, we expect research teams to have patients and other stakeholders on them. We expect them to be engaged from the beginning, formulating the questions and study design to be with the research team throughout the conduct of the research and to be with the research team as the questions of disseminating research findings are engaged. That's a criterion that is evaluated by reviewers and there are explicit instructions for how we want applicants to describe their engagement efforts.

The second component is a dissemination and implementation assessment. In our instructions, we say that you must talk about the prospects for disseminating these findings. Which stakeholders have you engaged so that dissemination will be facilitated? What are the facilitators that you know of and what are the potential barriers to dissemination and implementation? And that is assuming that the findings merit dissemination, not everything that gets funded will lead to a need to disseminate or particularly to implement, but assuming that they will, tell us how you see that happening.

The third area is an area that's very near and dear to the Methodology Committee and to the Board and we call it "reproducible and transparent research," and essentially what is means is that we want to comply, and, in fact, we want to be in the lead in the growing international appreciation of the fact that up to this point in time, research has appeared and in many cases it's been adopted and implemented using a set of processes that have

bias built in, that research tends to appear if the results turn out one way and it has a lower probability of appearing if results turn out another way. This takes place both at the level of the researchers and what they choose to write up. It also has to do with how they write it up and which findings they choose to present. It also takes place at the level of journal editors and what journal editors chose to publish and what they require of researchers as they present the data.

So, we come out strongly in favor of two things: We say that every applicant must agree to and tell us how they will at the end of the research produce a research protocol, programming code, annotations of what that programming code means, and data definitions in an inventory of variables. This is for all applicants. That allows others throughout the country or the world to take what we did and apply it to another dataset to see if they can replicate what we saw in another population. Very important because chance plays a role in what gets published and we want to make

sure that those findings really can be replicated in other populations.

The second part of this has to do with data sharing. This is a much more complex issue. Others have tried this and have found that it is complicated for many reasons to get investigators to share data and it's not only that investigators are reluctant, there are real logistic hurdles. So, we come out in favor of it. We asked applicants for particularly large amounts of funding that is over $500,000 a year in direct costs for any year to write a data sharing plan. We say that if we think it's important for you to share your data, we'll consider providing additional funding and we also allow for the possibility of a waiver in case these data have either proprietary interests to a particular health care system or whether there are concerns that the privacy of patients just can't be protected given the research topic.

So, that's our plan. We recognize that it's got to be flexible. We've got to evolve it in

collaboration with the research community and we have hopes of evolving it also in collaboration with NIH and AHRQ and in collaboration with journal editors, but we want it to put a stake in the ground that we think it's important and we have some modest requirements.

Then the PCORI criteria, which I'm going to introduce you to in a minute, which come from the legislation and which we think comes about as close as anything to saying what PCORI is genuinely most interested in, what makes it patient-centered and what it makes it of interest to us in terms of its potential impact. We also referenced the methodology standards and as our discussion this morning informed you, we have included multiple references throughout the application guidelines to the Methodology Report, we urge applicants to confer with it because it is good practice.

We do say that because it is a draft, you will not be held accountable to specific standards in the report, however, I think the fact that we urge them to take a look at it means that we

believe that when they look at it, they will see a record if they are not already aware of this of good practice in this area. Then in each Funding Announcement, we give the specific purpose, we have a background section, we list our broad areas of interest, which I'll show you, and we have exemplar questions, which are simply example questions that we think would be appropriate under this Funding Announcement. We go to great lengths to say these are just examples and by no means are a definitive list of what we're interested in funding, but we want to use the questions to kind of give a sample of the breadth.

So, here are the PCORI review criterion, and, as I said, these come from the legislation. They look quite a bit like what's in the Research Agenda, but they have been processed a bit to make them more useful to the reviewers and to the applicants.

The first is the impact of the condition on the health of individuals and populations. This speaks to the incidents and prevalence of the

condition, it speaks to the severity of the condition, it speaks to suffering of individuals, it speaks to costs incurred by the nation and costs incurred by individuals. That's the impact or burden of the condition.

The second is called innovation and the potential for improvement. So, we are interested in innovative methods, which because they are innovative populations or innovative studies and that they consider new outcomes, because we think that innovation will help have an impact on practice and patient outcomes, this criterion also includes evidence from systematic reviews or from guidelines development processes that this information is needed. It includes expressions from patients, patient organizations, clinician groups of the need for this. It also includes a consideration of how likely this is to be disseminatable and implementable. So, this covers a lot of ground, but we want to make sure that this research will have an impact.

The third is impact on health care

performance, so, either at the patient level or at the system population level. Does this research, this comparison have promise of improving the efficiency of care, and efficiency is outcomes and for the investment of time and resources.

Patient-centeredness is does this ask the question that's really important to patients? Are the comparators appropriate and of interest to patients and are the outcomes being measured important and have the investigators included patients and other stakeholders on the team?

The fifth is rigorous research methods and we go to great length to talk about what's important in methods. We also point them, as I said, to the Methodology Report.

The sixth is inclusiveness to different populations. As you know, being able to evaluate the effectiveness of interventions and the relative effectiveness in different patient subgroups is a very important aspect of PCORI's mission. This could also include studying effectiveness in a population that's never been studied before. So,

we may know how it works in some groups and not in others.

The seventh is a traditional criterion at NIH, AHRQ, and elsewhere in reviews, tell us about the research team and the environment in which the research is being conducted.

And the eighth is: Is this cost effective use of research resources? Is this an efficient use? Are we getting good return on our research investment?

So, those are the criteria.

Each PFA remains -- I put the word “broad” in quotes because it’s specific in some ways, but it’s certainly broad with respect to our interest in a research study of any condition or a cross-cutting question, which includes patients with a variety of conditions. It points out our special interest in patients with rare diseases. It uses vignettes drawn from focus groups that we conducted about the research agenda just to make the whole purpose of the funding announcement more salient and it emphasizes in every funding announcement

outcomes that matter to patients.

So, that, I've just talked to you about the general features of the Funding Announcements and the guidelines and now in the next four slides, I just want to briefly take you through what we said are particular areas of interest. So, under number one, "Assessment of options for prevention, diagnosis, and treatment, we said we're interested in research that compares effectiveness of two or more strategies for prevention treatment, screening, et cetera. We are interested in comparisons of the use of prognostication and risk stratification tools, which help get at individuals' risks in likelihood of benefit and how that compares with usual clinical approaches to making treatment decisions.

We're also specifically interested in studies that investigate key individual determinates of outcomes. So, you make a choice for one treatment or the other who in particular did better and not so well with each treatment choice. So, again, honing in on what works for me,

what works for an individual.

And, lastly, this PFA emphasizes that studies must be conducted in "typical clinical populations," that is real-world populations, must consider a full range of patient-centered outcomes and must account for possible differences among patient groups.

This is the second PFA on improving health care systems, and here we said specifically that we'd be interested in research that compares alternative system level approaches to improving access to care, the receipt of evidence-based care, the safety of care, we're interested in system level approaches to supporting personalized decision-making and self-care. We're interested in systems approaches to coordinating care across various health services and settings and we're interested in efficiency of health care and reduction in the use of ineffective, redundant, wasteful care. We're interested in system-level efforts to improve the timeliness of referral and particularly the timeliness and safety of

transitions in care.

Some of the approaches that systems might use are called out, applications of Health Information systems and Electronic Health Records, patient portals and personal health records, incentives directed at clinicians, incentives directed at patients, new roles for Allied Health Professionals, always emphasizing patient-centered outcomes.

Third PFA on communication and dissemination research, we called out particularly comparisons of approaches to increasing the awareness of health care options among patients, caregivers, and clinicians to encouraging patient, caregiver, and clinician participation in shared decision-making to taking care to elicit, to draw out individual patients' desired outcomes and preferences for specific outcomes in health care decision-making processes.

And, lastly, in approaches to providing new information to patients or caregivers and clinicians via more novel approaches, public health

approaches for use of social media. So, those were the specific areas we cited in this one.

And in addressing disparities, research that compares alternative approaches to reducing or eliminating disparities. Not describing disparities, not reporting disparities, not seeking particularly to narrowly understand disparities, but efforts to eliminate disparities or reduce them.

Efforts to reduce the impact particularly of socioeconomic, demographic, and community factors on clinical outcomes; so, accounting for those efforts to overcome barriers that patients or providers or systems experience to identifying and making the preferred choices in each category of decisions, and information-sharing about treatment outcomes in Patient-Centered Research in various populations.

So, those are the specific areas that the Funding Announcements call out and with that, I'll stop and see if we have a little time for questions before I turn it over to Martin.

CHAIRMAN WASHINGTON: Okay, well, first, thank you, Joe, and also my thanks to all the Board members that have been involved in developing the various components and particularly those of you who also made the extra time available and effort to review the actual draft PFA.

And so, we have Ellen and then Arnie and then Michael to start.

DR. SIGAL: Ellen Sigal, Board.

First, a thank you. This is what we are about, so, I'm extremely happy that we're going to really have research that is going to impact patients and with outcomes that are important, but my question is a little bit about how we're going to facilitate nontraditional outreach. Now, I know we're going to do webinars and we're going to try to get nontraditional people than the normal people that apply for these grants involved in it, but what support are we going to really have at PCORI to really help the nontraditional people that really can help us answer these questions because we're not known very well and there are people

outside of the academic population that really may need help and what can we offer them? So, I guess that's the question.

And the other question is: Can we get patients? So, there may be some very good questions, but without sufficient patient groups that are involved, are we going to be able to mix and match or be able to help support some very thoughtful grants, but don't have sufficient patient involvement in them because at the Stand Up to Cancer, which is an interesting model, the part of it that I like a lot is they're able to mix and match, they're able to take the best of some proposals and really mix it with other proposals and really do something. So, I guess that would be my question: What can we do?

DR. SELBY: Thank you, Ellen. That's a question that's of great concern to us on the staff and we've had a number of conversations about this. I would say that it is in our plans to become extremely good at we call it matchmaking. When we see researchers without the appropriate patients

and stakeholders involved in their research to help them and particularly when we find patient groups or other stakeholder groups that need to be linked to researchers.

The process as we think about it, it's complex and, also, we have in mind an anticipation that we're going to get a lot of applications, a really large number, and our staffing is going to be increasing, but not probably full strength during this first round. So, this is something that we can try to do through the Letters of Intent process, the Letters of Intent, which you'll hear about from Martin, does give us some information on both the ideas, the research idea, and the composition of the team, but I think it's something we're going to have to evolve over time, especially with our engagement folks and the input from the Board so that these processes get better over time.

CHAIRMAN WASHINGTON: Could I just put on my board member cap, taking off my chair cap for a minute? I think we're going to need to be a little bit more proactive about what Ellen is describing

now. I just think if it evolves over time, it'll be three years down the road and we'll have been through four or five cycles and we will have not, I think, reached beyond the usual suspects and what you just described I don't think gets us there, and so, I'm going to throw out that I think we need to literally have a plan that's got multiple tiers.

I'm putting on my board member cap now, but that begins to lay out sort of the different ways or the interventions that we're going to employ, and someone mentioned earlier, that's part of this other infrastructure that we want to develop that's beyond the research. Yes, that's very much part of that infrastructure, but I think that that's going to require a focus, a concerted finance effort in order to make that happen and that it's just not going to happen organically. And so, we need to think about how we make that happen. Comments on this particular --

VICE CHAIRMAN LIPSTEIN: Yes, Ellen, in your observation, when you looked at the Pilot Projects, were those the usual suspects or did you

see anybody in that pool that was out of the ordinary that surprised you?

DR. SIGAL: It seemed more or less the usual with a little bit out of the box, but these are technical questions that we're asking, the PFAs, certainly in the research. Some of the others may be a little bit easier, but it was more or less the same, the people that are really equipped who really have infrastructure in place and know how to do this. This is how they earn a living.

So, I agree with Gene. I think we have to do better and I think we have to be proactive and I think we have to offer support to those who -- I had a personal story that I told Joe about a week or two ago about a cousin of mine who actually didn't know us and has the type of outreach that we need in family medicine. So, we have to figure out how to work this and support them.

CHAIRMAN WASHINGTON: Okay, is it about this Christine?

DR. GOERTZ: It is.

CHAIRMAN WASHINGTON: Please.

DR. GOERTZ: Just a couple of things. First of all, as far as the Pilot Projects go, not necessarily a good barometer for the types of applications that we might receive because that was really more based on methodology and you'd expect more of a scientific group to be responding to that.

My second point is I agree completely about needing to be proactive about this and NIH has actually done this very well, I think, with complementary and alternative medicine and by putting out specific announcements that forces different types, different groups to pair together in order to receive funding. It really goes a step beyond what we're doing now and I think that that's a model that we can look to as we're moving forward with PCORI.

CHAIRMAN WASHINGTON: Arnie and --

DR. EPSTEIN: I pass.

CHAIRMAN WASHINGTON: Arnie's passing. Michael and then Leah, and then we're going to come

to Sherine.

DR. LAUER: Mike Lauer, representing NIH.

So, this is really terrific. I was wondering if you could briefly tell us, Joe, how you plan to operationalize all of these many criteria, public health burden, innovation, impact, rigorous methods, inclusiveness, research team, efficient use of resources. How is that going to actually happen?

DR. SELBY: It's included with in-depth descriptions of each criterion in the application guidelines. The application itself, the format for the application calls on you to respond to each one. And the reviewers will be trained and the scoring will follow these criteria. So, rather than CSR scoring, which has, as you know, five criteria, we go to eight.

CHAIRMAN WASHINGTON: Okay. Leah?

MS. HOLE-CURRY: Leah Hole-Curry, Board Member.

First of all, great work. I think if I see any theme developing from the topics that we've

discussed, it's recognition that this is foundational and a huge amount of work has gone into it and I am personally amazed, but also that it is foundational and we aspire in each one of these to move it forward.

So, first of all, I think the user-friendliness is much improved. So, thank you. That was a concern of mine in getting to the nontraditional researchers, that's one component of it.

As we alluded to this morning, I have a concern about the methods and also the openness by which we publish and share both the proposals and the data. So, I don't think for the Board discussion I want detail about all of those except to say that I come back to Gene's point that was specific to the outreach and I sincerely believe we need a plan to evaluate how we're doing in terms of our PFAs against some measures that we all aspire to, including reaching nontraditional sources, but others, too, like how open we're being, what methods are being utilized, et cetera, and that

that be brought back to hear because I think we have this amazing opportunity to leverage funding and when you put something as a requirement in funding, it's phenomenal how responsive that can be.

[Laughter.]

MS. HOLE-CURRY: I'm not saying we know all the right levers to push right now and I'm very happy with this foundational document, but I really think that there are more opportunities and I just hope that we actually make a plan about how to ensure that we get to those opportunities.

And then just specific to the methods, maybe I'll wait for Sherine because I do think there's a middle ground about the Methods Report that we can make sure we telegraph appropriately so that we're not surprising anyone that applies, but that we use and instruct our reviewers, if appropriate, to have read the Methods Report and apply at least the principles that are in the Methods Report in assessing technical merit. So, and I'll pass that to you because I've heard that

the Methodology Committee may have concerns just in terms of timing or something else about that.

CHAIRMAN WASHINGTON: Sherine, you were up.

DR. GABRIEL: Yes, well, that was actually the comment I was going to make and just in response to your comment this morning, Leah, and actually in response to e-mails I received from Methodology Committee members who are listening who seem to be concerned that my message wasn't as clear. So, let me try and make it as absolutely crystal-clear as possible.

So, in no uncertain terms it's our expectation on the Methodology Committee and, in fact, it's in black and white in the statute that the standards that we put out, that applicants will need to be held to the standards that we put out there and that reviewers will need to be instructed on how to use those standards to review applications. So, I just wanted to make that absolutely clear that's our expectation, that's what the statute says, that's where we must go.

Now, the only discussion is and really it's a board decision, so, it's up to all of you, but the discussion is well, the timing isn't quite right, the report is draft, the PFAs are going out next week, how can we be fair to the applicants so that we're not holding them to something without giving them enough time to review it? But I just wanted to make that very initial point absolutely clear. That is our hope. We would be very disappointed and I don't think we'd be compliant with the statute if that didn't happen; it's just a matter of timing, when do we hold the applicants' feet to the fire, when is it fair to them and fair to the reviewers to do that?

MS. HOLE-CURRY: Weren't some of your criteria though that these are already commonly accepted within the research community and implementable? I mean, at least foundational for me in terms of whether there's a fairness issue to holding someone to a standard that they may or may not be currently aware of. I believe that was in your criteria.

DR. GABRIEL: Yes.

MS. HOLE-CURRY: And that, again, feeding off this foundation, the Methodology Report is an amazing compilation of work, but it's a foundation, some of the more controversial recommendations that might be made are not in there.

I feel like we don't necessarily need to change the PFAs to get at this issue about expectation that our reviewers are looking to that as their guide when they're assessing technical merit.

CHAIRMAN WASHINGTON: Yes. Okay.

MS. HOLE-CURRY: Maybe that's a context setting or something else we can do.

CHAIRMAN WASHINGTON: The decision is right now whether we want to take this question on. Why don't I just park this for a minute? This is a question that's on the table and we're going to come back to it. So, if your questions are related to that, I want to cover other points. We're going to come back to this specific question. Okay, and, also, Martin's got a presentation, remind me. So,

even more reason why. We're going to come back to this question of what is the degree to which we're going to hold responsiveness to the PFA, to the standards which even though they're "in draft form," they're available in evaluating applications. So, that's going to be the question.

But with that, I'm going to start with Harlan W., and then Christine, and Allen.

DR. GOERTZ: Mine was actually on that topic.

CHAIRMAN WASHINGTON: Okay. So, if you don't mind, we're going to come back to that.

DR. WEISMAN: I'm going to take it away from that topic. Joe, I brought this up in our phone calls and it's the $500,000 rule, which I said I'll support. So, I mean, that's not an issue, but I did feel compelled to talk about it in that, our criteria, the ones that you went over that Mike was asking about is that our criteria say that the research, no matter what the funding level, should have impact on the health of individuals, innovation, and potential for

improvement through research, impact on health care performance, et cetera. So, that means everybody we give money to, no matter what the amount, we believe is important and deserving of funding and has its potential impact, whether it's a $500,000 grant or it's a $100,000 grant.

So, it's not clear to me why we differentiate in terms of expectations of transparency. The tie-in to the later discussion, I guess, is that the Methodology Report emphasizes in several different ways both in the text and they put a black box warning is what I call it to the Board saying they really want to encourage the idea of sharing of study protocols. I think you said that for everything. Statistical code and data for everything that gets funded and they recommend as a board that we create some kind of committee to put that in execution. I don't know how to phrase it. I'm just uncomfortable that the two ideas, the idea that this should be economically driven by the size of the grant isn't at all clear to me why we're doing that. But I do understand you told me that

there are other board members who feel just the opposite of I do and that it's onerous and we shouldn't put that burden on people.

DR. SELBY: I think the differences of opinion have to do explicitly with data sharing or primarily with data sharing and just with the proven logistic complexities when you try to put it into practice and that creates more of a go slow approach. I think it's one of the things that we need to as a board and an organization continue working on and it may be the topic of a work group that we convene. We've had some conversations about that.

In fact, it's a complicated issue, as I said. I think everybody wants PCORI to be out in front on it, but we don't want to get so far out in front that we haven't thought through, that we say something and put out a requirement that we can't even live up to yet.

The $500,000 is consistent with my understanding with the way NIH is doing it at this point and it kind of says if you're going to spend

money on data sharing and data sharing typically costs some more money, you should probably do it particularly on the bigger projects.

CHAIRMAN WASHINGTON: Okay. I have Allen and then Sharon and Gail and then we're going to go to Martin's presentation. Please.

DR. DOUMA: Yes, this is a little bit of a follow-up to Michael's question about the review criteria and the process for scoring. We have a number. I don't know what the number is. But this is a little nested question; so, let me ask two before you respond to the first one and that is: Have we determined the relative way to value each of those criterias compared to the others? And probably the one that's going to be the most difficult, but it's also the one that sets apart the most is patient-centeredness. Do we have decisions with regard to what are the various outcomes that we think makes something patient-centered?

I mean, specifically, what would a reviewer look for in a research project and I

presume there's a list of those outcomes and are they all of equal weight or are some more important than others? This is not 1984. So, if you could talk about sort of the weighting of criteria and how we go about the process of doing that.

DR. SELBY: There are not weights. Reviewers are asked to score each of these criteria and then they're asked to give an overall score, which is not, in fact, an average of the eight individual scores; it's an overall score. You can imagine that it's going to be pretty correlated with the average, but it's not the average and that means that you leave some of the decision-making up to the individual reviewer to do weighting in their head rather than us putting a weighting on it upfront. I mean, that's pretty much the way it's done in other settings.

DR. DOUMA: Okay. Just a quick follow-up to make sure I heard this correctly, in taking the patient-centered, we will have some kind of training for the reviewer --

DR. SELBY: Yes.

DR. DOUMA: -- to say these are things we think are important in the patient-centered bucket, take a look at it and give me a score, we won't guide them on how to evaluate each piece in order to score that bucket.

DR. SELBY: That's right.

DR. DOUMA: Okay. I would just suggest that at some point I think it would be a great intellectual exercise for us to actually do that.

DR. SELBY: What we can do, and Martin will tell you about the database where all this will reside, and NIH has done this to some extent, too, we can look at how the individual component scores correlate with the overall score, and at NIH, the component score that correlates the strongest is the approach or the methods. We did find in the Pilot Projects that there was a very nice correlation between patient-centeredness and the overall score.

CHAIRMAN WASHINGTON: Before we go on, Sherine has a related comment.

DR. GABRIEL: Just a quick response to

your question. Of course, the working group within the Methodology Committee that Ethan and Mary shared on patient-centered methods addresses exactly those questions and we have a list of standards -- I don't have the book in front of me, but Harlan was waving it towards me when you were talking and there are some standards in there about what does it mean for a question to really and truly be patient-centered? What does it mean to involve patients in every step of the research protocol? So, we do have standards on exactly that question.

DR. WEISMAN: On page 25.

DR. GABRIEL: On page 25 and 26.

CHAIRMAN WASHINGTON: That's great.

Okay, next, we have Sharon and then Gail and then we're going to go to Martin.

DR. LEVINE: Just a quick comment, Ellen's and then your comment, Gene, around outreach to nontraditional potential research applicants really highlighted for me that one of the missing pieces around our engagement strategies is we haven't done

anything explicitly with the research community. We're got a plan for patients, we've got a plan for physicians, we've got a plan for public policymakers, but we haven't looked at building out an engagement strategy for traditional and nontraditional researchers in terms of stimulating interest in doing this and building partnerships among them probably needing to be community-based efforts, site-based. So, just for Judy sitting in the background there, we really need to add that to our agenda to flesh that out.

CHAIRMAN WASHINGTON: Excellent point.

Harlan, related?

DR. WEISMAN: Just real quick, because I forgot to say it and it's something similar to what Sharon was talking about. We have a built-in group of nontraditional groups that we have connected with and that's in the various cities like New Orleans, Seattle, Saint Louis, Jacksonville.

Using New Orleans as an example, we met with the community health center group there that is doing research and I think that's at least a

natural set of groups of people we've met or the Native American groups in Seattle that we could reach out to because we've already connected with them and maybe we should at least make sure that they know about this and we're tying back to them.

CHAIRMAN WASHINGTON: Okay.

Gail?

MS. HUNT: Yes, Gail Hunt, Board.

I just wanted to make a pitch strongly that, again, we think about innovation because especially after I heard what you were saying, Ellen, about same old, same old, and it's not just "usual suspects," I mean the methodologies and the issues that they're going to study should be innovative because that's part of what should be branding us that we're really out there funding innovation.

CHAIRMAN WASHINGTON: Okay, please go ahead.

DR. SELBY: Okay, so, I am going to turn this over now to Mr. Martin Dueñas, who's PCORI's Contract Manager. Martin played a really central

role in getting the applications' guidelines together, getting this all ready for the web and behind the scenes, getting the database in place that's going to handle all this. As you know, he came from the Juvenile Diabetes Research Foundation, where he did similar work for a number of years and Martin's going to talk to you about the very interesting review process.

MR. DUEÑAS: So, this session is basically informational, so, there's no decision, and as everybody's been mentioning, this is the starting point, so, the foundation. Hopefully, we'll move forward from here.

So, the agenda, I'm going to talk about the two-stage merit review process that we will do for the PFAs that we are announcing. I'm going to specifically go over the goals and the key attributes of this merit review process that we'll be doing. I'm going to briefly explain the two-stage merit review process, I'm going to tell you how we're going to do it from the administration point of view and I'll give you a projected

timeline.

As important as it is to tell you what I'm going to talk about, it's important to tell you what I'm not going to talk about, but there will be questions, important topics in terms of the training curriculums. Everybody's been talking about reviewers, applicants, different training venues that we're going to utilize. The only system I will talk briefly in the application process prior to the review. I will briefly touch on that, but I'm just going to focus very briefly in the review process that we're going to do. It's a very complex process, and I'm going to try to simplify it as much as possible.

So, what's the goal of this two-stage review process that we'll do? There are many goals and so many board members; there will be as many different ideas of what the goal will be. But, again, I think the basic thing is to establish a rigorous peer review process that assures that PCORI's funding the best possible science out there. This process is going to provide a forum

for the patient stakeholders to have a clear and valued voice in the decision-making process.

Now, at the end of the day, I think it's good to determine the potential of the research that's being funded in terms of the patient-centered health care and landscape out there. What are the key attributes to this two-merit review process? Let's be clear in terms of the first one, operational. We're going to be funding these four PFAs. There's going to be a large volume of applications, we think. So, this is going to allow us to basically review and evaluate those proposals in a very efficient process and it sort of offers growing operational needs.

We think that this process is also vital to identifying the best research that is patient-centered. And, also, as I mentioned before, it's going to provide the forum for the patient stakeholders to be a direct part of the funding decisions.

In a very simple way in a very complex process, this two-stage process that we're going to

use has two phases. The first phase is going to be a scientific/technical review and a phase two will be an impact review of those applications. I will go into a little bit of detail what that means.

I mentioned some of the things that I was going to talk about and some of the ones that I'm not going to. So, these slides, and it changes a little bit from what the distribution was, so, please look at the screen, shows you a little bit what the entire process entails from application to the approval. I will touch a little bit in the application process about the new online system that we have. A little bit about the approval process at the end, but I'm going to focus on the merit review, which it has these two phases that we're talking about.

So, the next slide summarizes the two phases that we're going to be using for the review of these applications. So, the phase one is an e-mail review. So, we're going to get all these applications, we're going to send that out for review. What we're trying to accomplish on the

first one is we're trying to accomplish an in-depth science review of all the proposals.

So, that's the goal, simple. Phase two will be an in-person review. The focus is going to be patient-centered outcomes research and it's going to be in the impact of the proposals that are being submitted.

So, that's the two-stage process in a nutshell.

The last part of the review process will be the PCORI approval form and similar to what went on during the Pilot Projects, this is going to be a business review in terms of budgets, funding overlaps, and these issues like that. There's going to be a balancing criteria that we use in the Pilot Projects and then after that, a progression of recommendations of the applications to be funded for approval for the Board.

So, what we think is one of the key issues in this two-stage process is the patient and stakeholder involvement. So, the approach to this will be, and let me just read it to make sure we

all understand it. The patients that hold the reviews are part of the decision-making process and all reviewers will be trained in PCORI's missions and processes to advance patient stakeholder engagement.

So, what are their roles? The role is going to be review the proposals to make sure there is patient stakeholder involvement. And what's the impact of the patient stakeholder engagement? So, it's going to ensure that the patient stakeholder perspective is included in the merit review process, it's going to ensure that the patient stakeholder engagement is also included in the entire research proposal and as well that it has a direct relation to patient-centered outcomes. So, this is one of the key issues.

In order to accomplish that, and this, as I say, I'm not going to talk about this, but just briefly because it's key and it's been mentioned several times already, we need to be able to train the patient stakeholders. There's a complete curriculum that is being developed as we speak that

is going to train the patient stakeholders in the different areas, especially centered outcomes research, national priorities; the actual Program Funding Announcements, the actual application form, and as we mentioned before, the critiques and the format of the scoring of the entire process.

How are we going to do this? There's many ways that we're going to do this, try to, and it's going to take a lot of time, it's going to take different sessions. Some of the three that we know that we're going to use is going to be an in-person training, there's going to be some webinars, and there's going to be some videos, as well.

As I mentioned, this is a very complex process. How are we going to do it? Right now, we have assigned our PCORI project manager, internal consultant. NIH is still providing support and we have a project manager for NIH, and PCORI is going to contract the SROs directly. NIH was doing it for the Pilot Projects, now we're going to do it.

The basic responsibilities of which people in this process, the PCORI project management would

oversee the overall management of the review, NIH project managers, they come into PCORI every week and we talk to them on a weekly basis to give us a guidance on anything that we might be missing. Then at the end of the day, the scientific review officers would preclude the reviewers, conduct application quality controls, lead the application assignments, oversight on panel one and two for the reviews, drive the summary statements, support development of training, and material to conduct the training.

This is a snapshot of one of the screens of the new PCORI Online System. For the Pilot Projects, the NIH System was use. This is a new system that we're implementing. We're actually testing it as we speak. We're going to load test it early next week to make sure that we hit it with a lot of applications only one day so that we know that it will withstand depending on the load of applications. The system will be able to capture the submission of the LOIs, the submission of the applications, the submission of the applications,

and the submission of the reviewers' critiques. It will also be able to store the summary statements and will also do the proposal management.

It will help us in terms of management on some of the reportings that's been requested lately in terms of the different aspects of applications, funded applications, not funded, different stage, different areas. So, we will be able to have that immediately and possibly down the line online for everybody to see.

So, what are these advantages of PCORI overseeing this review process? As we mentioned and has been mentioned throughout the session here, there's going to be an increased patient stakeholder input, it's a great opportunity to guide the review process from PCORI's view. I just mentioned the greater flexibility in terms of external reporting since we're going to have the data and own it and one of the key ones, I think, is enhance the good relationship with the scientific/technical patient stakeholders reviewers for future PFAs.

So, when will all of this happen? It's happening as we speak. We're going to be launching the PFAs today. Did everybody get that?

[Laughter.]

MR. DUEÑAS: The Letters of Intent will be due on June 15th. I know, it's soon. The full application will be due July 31st. Once we get all the applications, we'll do an internal control and make sure that the applications meet the administrative requirements, make sure that it's addressed in the PFAs that we launch, make sure that it has the administrator that is dividing funds, so, internal issues that we need to do. Once we accomplish that, we'll send it out for reviews. That will happen somewhere between August 15th and October 1st. Then we'll have the in-person review. We're projecting that review to happen November 12th, and then once that happens and everything is electronic, we do some internal massaging in terms of getting the data for everybody to analyze, then we'll analyze it internally and then we'll bring it for approval for

the Board.

So, I just went through a few minutes a very complex process and I see everything going out for questioning.

[Laughter.]

MR. DUEÑAS: Which is fantastic because, again, everybody is talking about 1.0. This is 0.25 and the more questions that come up, it will give us a little more information on how to do this better now and in the future.

CHAIRMAN WASHINGTON: Thank you very much. [Off microphone.]

DR. ZWOLAK: Oh, okay, thank you. Bob Zwolak, Board Member.

This is fantastic, but as I listen to this, I'm sitting here trying to think of how the process would work for the nontraditional investigators. So, this morning, we heard the methodology standards, fabulous something of pretty high-class, complex standards, and, today, we just now heard Martin mention the word "complex" in terms of evaluating these applications efficiently

and we hope for hundreds if not thousands of applications.

So, what I see is the system is set up for the very sophisticated submissions by established investigators, which, in fact, is probably where the best bang for our buck will come from most of those, but simultaneously, I see the system as almost automatically washing out the newbies who are overwhelmed by the methodology standards and when they get to that efficient electronic review process, where our reviewers are probably going to have hundreds of them to look at, phew, they'll be likely gone.

And so, is there a detour path? Is there a button to push where the reviewer is going to say whoops, this is special category, we need special consideration of these, and if we do that, realizing that they will be enormous potential resource syncs are we going to set up kind of a special pathway to look at those and try to figure out who we're going to help and how much we're going to help them?

MR. DUEÑAS: Can I take a stab at that?

CHAIRMAN WASHINGTON: Sure.

DR. SELBY: Sure.

MR. DUEÑAS: So, a couple of things and let me just try to understand. One question will be: Will the system allow the nontraditional applicant to submit? So, one of the big things that we're trying to do is to make a very easy one, two, three-step process to apply. So, the system itself will be very easy to use. You still need to submit the required material, but a lot of it is easily just entering and uploading. So, we hope it will be -- we're testing it with a lot of uses right now to make sure that we get the feedback and tweak it to make sure that would make it easier.

The other thing about the reviewers, we're hoping to have no more than five applications for reviewers so that they don't sit through the thousands of applications. So, the reviewers will be focused.

DR. SELBY: Just I wish Sharon-Lise was here right now because she likes to point out that

we generally are committed to doing this research using rigorous methods and the reason is because if CER research or any research, but particularly CER research is not done with rigorous methods, it winds up not having an impact. So, it points up the importance.

You're right, it's going to be tough to follow all the methodology, committee recommendations if you don't have some experience. So, that really brings this notion of matchmaking of linking community members, patients, clinicians, organizations that aren't steeped in research methods and tradition together with researchers who are. So, I think that's the only answer.

We've had conversations with PCORI about how's that going to happen? I mean, can you really match somebody in Rochester with a patient group in Mobile, for example. It probably is going to happen within communities as much more often than not. So, how do we facilitate that? I appreciate and welcome the Board's encouragement to push this faster, but that's what it's going to take, I

think.

CHAIRMAN WASHINGTON: Okay, I think Leah's comment is related to this point.

MS. HOLE-CURRY: It is related. One practical way to potentially do that is to continue to have the phase one and phase two. I want to underscore my support for scientific rigor, but if you had in phase one the review by the stakeholders of what's important and then the scientific review to ensure that what got funded, that would be one way to do it, and those that don't get funded, but pass the stakeholder review could then go to the funnel you're talking about for a matchmaking or, I mean, it may be that outreach back to them about look, you have an important impactful question, but we still need to match it to scientific rigor, here's four options or what that is but that might be one way to do it is to flip the mail review. It would still have to go through the scientific check, but the first gate would be the stakeholder importance piece.

CHAIRMAN WASHINGTON: Okay, we have a

comment, yes. One of the first things they teach you in sort of Chair Lesson 101 is you're not supposed to take off your chair cap more than once in a meeting and I've already done it. But I want to do it one more time.

UNIDENTIFIED SPEAKER: 101.

[Laughter.]

CHAIRMAN WASHINGTON: Yes, good, thanks for reminding me that.

Yes, no, but just picking up on that point, there are ways that you can make adjustments even now. I mean, for example, NIH, one of the ways that they sort of make up for the handicap with junior investigators is they give us priority to junior investigators. So, one could be, not that I'm proposing this, is some small proportion goes to somebody who never applied before. I mean, I'm just throwing that out as an example or some proportion, and I don't remember whether it was HRQ, some years ago, the primary grant couldn't go to you in academia.

Trust me, we left and jumped across town

because the primary grant, some portion of it could only go to a community organization. It changes the dynamic, and so, I was sitting here thinking as the tension between the timeliness and inclusiveness, but the truth is, there's some things we can do right now, stay on our schedule, but begin to signal even more powerfully that we're taking this serious and it's not going to be business as usual.

Okay, I'm putting my chair cap back on now, which means I can be back in charge, Gray.

[Laughter.]

CHAIRMAN WASHINGTON: But, Gray.

DR. NORQUIST: Yes, this is related because it's too bad Christine left, but yesterday, Christine and I met with Martin about this, and we actually proposed this very thing that you're talking about because what my problem is is that if you have a filter --

UNIDENTIFIED SPEAKER: Can you talk louder?

DR. NORQUIST: Yes, it's on, but for

some -- if you have a filter in which you only let the most scientifically-rigorous come through, you're going to lose a lot of the innovatives. There's no question. I mean, I saw it when I was at NIH. You can't do it after the fact because if you're going to get tons of applications, you have to have some filter in order to get some you can actually review, but if you do it really on scientific rigor initially, we're going to have some very rigorous studies that might be kind of boring, to be quite honest, from an impact factor.

So, I agree, but they have a problem in the way their system is set up and how they can start to whittle down the grants, which I think is forcing them to some degree into this because your system is set up to find the reviewers by what their scientific expertise is.

MR. DUEÑAS: Do you want to go, Joe --

DR. SELBY: So, we were persuaded last night, except that, yes, we're not going to switch and say impact first and science second. We want to be engaged in both. So, we want --

DR. NORQUIST: But then you need to say that because --

DR. SELBY: That's right. Right, so, in other words, the slides didn't get changed today, but I think we are persuaded that even the first round needs to assess impact and patient-centeredness and have patients and stakeholders involved. We can then between the first and second round, we can look at the scores on both; we can look at the scores for the science, we can look at the scores for patient stakeholder engagement, and innovativeness and potential for impact and chose these cutoffs that don't strictly go take the top whatever number of percent based on scientific rigor alone. So, we were persuaded by what you said.

MR. DUEÑAS: I did mention that the first phase was going to be scientific rigor. I didn't say what the panel will be and that's why we were persuaded and we're looking at it. So, it's open right now. We might be able to bring patient stakeholders for panel one.

CHAIRMAN WASHINGTON: On the same point, I saw Harlan's -- any other comments on this particular point and then I'm going to keep going, Arnie.

DR. WEISMAN: So, Harlan Weisman, Board Member.

I really like the things you said, Gene, and you speak out of experience and knowledge and I'm speaking out of total naiveté, but what I was imaging when I was listening to the problem, and this would be true whether you invert or not invert is is there a way that we can create academic foster parents or big brother, big sister that we fund for the sole intent of having them play that role where they can work with and it's sort of a variant to what you were saying and maybe your way is better, but I don't know how much it would cost us to do that because even if we do patient-centeredness first and all that, they're still going to need help. We have to create a method of mentoring, a helping hand, and maybe we can just pay academic investigators to do it in some

fashion.

CHAIRMAN WASHINGTON: That's part of infrastructure building again, but, Arnie and then Larry.

DR. EPSTEIN: Arnie Epstein, Board.

I'm going to mostly actually ask for clarification rather than make a comment. The only comment I want to make is that these two issues are getting layered on each other, which is what's a reasonable way to review these proposals and how do we introduce greater collaboration, coordination amongst groups that have different levels of expertise? And this is one of those times -- I understand there were some relationships when I think if you dealt with them separately, you'd get greater clarity.

Having said that, I have very little clarity about what you're envisioning for the review process. I'm familiar with a number of two-stage review processes. So, for example, the RWBGA that does this routinely. You'll send a two to four pager, they'll look at it, and since they

don't have all the details of the methods, they're clearly just asking a lot of questions like is this in the ballpark and does it look like it's important? And if you pass that, they'll ask for a second. On other federal proposals now, you'll have people go off and do their own review and if you don't get to a certain threshold, you're not really going to get scored.

What is it you're actually talking about? What is the information they'll have? Who's on the panels? How are they going to make the determinations? What will be the criteria? What is the timing? I'm just not able to grasp it.

MR. DUEÑAS: So, we decided this PFA is very broad, so, the reviewers, the first review will have the entire application. So, they won't be an LOI review, it will be an application review, and they will have the eight criteria that Joe mentioned in order to score and give feedback on the application.

DR. EPSTEIN: So, who's on the review panel? [Off microphone.]

MR. DUEÑAS: So, the review panel is going to be -- can you hear me? So, the review panel --

DR. EPSTEIN: What?

DR. NORQUIST: When you were talking, your microphone wasn't on.

DR. EPSTEIN: I'm having trouble still. Who's on the review panel? Do they meet? What are the things they're being asked to look at? How will they rate them? What happens? It's totally Barney, I'm sorry to be so dumb.

DR. NORQUIST: No, no, thank you.

MR. DUEÑAS: The review panel, we're going to hire the scientific review officers, we're going to contract them out. They're going to select reviewers throughout the country with expertise in each of the PFAs. And when they're selected, they're going to be assigned applications and they're going to be given the criteria, the eight criteria that Joe described in order for them to score and give feedback on that application.

DR. EPSTEIN: Am I sitting by myself in Boston? Am I tied into a teleconference?

MR. DUEÑAS: Oh.

DR. EPSTEIN: Am I discussing it with Gray and Larry? Help me understand the details of what you're talking about.

MR. DUEÑAS: So, you're asking one thing is who are going to be reviewers and then the other one I think you're asking is: Are they going to be trained in certain ways?

MS. HUNT: How? How will they do it?

[Simultaneous discussion.]

DR. SELBY: So, I'll take a stab at it, but I think you know this reflects the fact that this is in process. This suggestion initially came to us from CSR, who employed a very similar approach with ARRA funding. So, they had a first round that was done by mail. People did not talk to each other. The highest scores there went to a second round, which was face-to-face. And that's the essence of it.

I think the suggestions that Gray and Christine made last night, we like a lot, which is to build in an assessment, even in the first round,

which is done by mail, where there is no teleconference, there is pre-review training. So, there is teleconference for pre-review training, but the reviews are done in isolation, the three are put together into a summary statement, and the second group has that summary statement to work with.

The second group, they again have scientists, as well as patients and stakeholders on them. They certainly are free to look at the science again, but they are asked to focus particularly on the likelihood that this will have impact and whether or not patients or stakeholders are engaged. At the end, we'll have the scores from both rounds.

DR. EPSTEIN: That's helpful. Thank you very much. It sounds a little like Study Section, in which we're going to take the bottom, call it tenth half, 60 percent, and we're just not going to waste the Study Section's time because when the pay line is at four percent, you're not going to make that kind of jump. That's okay. I do find the

comments that Gray and Leah made about the ordering war and I wonder whether you're going to have to divide up that way. Why one first and one second? It's just like the Study Section works, you've got a series of judgments.

DR. SELBY: I also like Gray and Leah and Christine's suggestion that we consider both scientific merit in all eight criteria, but that we pay attention to impact and patient engagement in both rounds. So, I like that, but you've got to get 1,000 applications down to a number that you can review, the highest, most promising on both metrics, both scales, scientific merit and engagement and impact and pick a smaller group that you can review face-to-face. You can't just fly thousands of investigators to Washington to meet face-to-face.

DR. EPSTEIN: I agree. So, the operant issues are really do you do it the way you just described or do you do it RWJish, where you say let's drop the entry price from 12 pages to 2 or 3 for the first one? I'm not trying to push us in

that direction, don't mishear the tone.

CHAIRMAN WASHINGTON: Okay, particularly on this question, first of all, is this clear now? Are there any questions about clarity because I'm still seeing some heads and also I'm teased about reading you all's faces so well.

[Laughter.]

CHAIRMAN WASHINGTON: But there's still some confusion, I can tell, from the group. So, let's at least slow down, if we have to, and let's hear from our two methodologists. So, Michael and then Sherine.

DR. LAUER: So, if I understand this right, the way ARRA was done, on both the first review and then the second review, all criteria were considered.

CHAIRMAN WASHINGTON: Would you tell the world what ARRA means?

DR. LAUER: Oh, ARRA, I'm sorry, is the American Recovery and Reinvestment Act of 2009, and NIH was given over $10 billion to fund projects and had a very short period of time to process these.

So, what they did was they went through an initial review, which was done entirely electronically. It was like editorial board style and that triaged down the number of applications that the study sections actually review to a relatively small number. And so, that's what made it possible to look at it must have been tens of thousands of applications and come up with a good package when all was said and done.

So, what I'm trying to understand here is that initially, you said scientific review first, then impact second. May I suggest at reversing it? But if I understand this right, what you're coming to is that both impact and scientific rigor will be discussed both times. Is that right?

DR. SELBY: I think that's right. Certainly, Christine and Leah in great suggestion says consider everything at round one and have representatives of patients and stakeholders as well as technical reviewers at round one. So, I think, Mike, although you put it into words better than probably we've even quite thought it yet, is

that we will look at all the criteria twice and I'm heartened that that's actually the way ARRA did it, as well.

CHAIRMAN WASHINGTON: Okay. Sharon and then Larry.

DR. LEVINE: I just have a dumb question, which is: Is there any communication to those who submit Letters of Intent back from PCORI between then and when the final application is due?

MR. DUEÑAS: So, there will be training and will be communication, yes. So, when they submit the application to the LOI through the system, there's going to be information, your application, your LOI has been submitted, your application --

DR. LEVINE: But it's generic, it's thank you for this interesting proposal?

MR. DUEÑAS: Correct.

DR. LEVINE: So, there's not specific to what they have submitted that goes back?

MR. DUEÑAS: So, after the review, then they will get feedback on the application.

DR. LEVINE: Right, but no feedback on the Letter of Intent?

MR. DUEÑAS: No.

UNIDENTIFIED SPEAKER: That's just [off microphone.]

CHAIRMAN WASHINGTON: No.

MR. DUEÑAS: So, what we're trying to do with the application and intent in this time is sort of determining how many applications we're going to get.

UNIDENTIFIED SPEAKER: [Off microphone.]

UNIDENTIFIED SPEAKER: Right.

CHAIRMAN WASHINGTON: There is an exception to this though. Would you point out the exception?

DR. GOERTZ: I believe our plan is that if they submit an application with over 500,000, then there would be feedback and discussion with those investigators.

MR. DUEÑAS: Correct.

CHAIRMAN WASHINGTON: Okay. Larry and [off microphone].

UNIDENTIFIED SPEAKER: Pretty much close --

CHAIRMAN WASHINGTON: You said close? Is there anybody on this because Sherine, your hand, I think, is on this particular point of the --

DR. GABRIEL: [Off microphone.]

CHAIRMAN WASHINGTON: Yes. Okay.

DR. GABRIEL: Yes, I had two points. That was one of them.

CHAIRMAN WASHINGTON: Okay.

DR. GABRIEL: I'm still a little bit confused about the two-stage process. I was planning to speak against it and the flipping helped some, and the reason I was going to speak against it is that if we are really to change the culture, we need to have the scientific reviewers side by side with the stakeholder reviewers to hear what one another says and to have an opportunity to change their minds based on input of the other ones. So, without an integrative process, we're not going to get that and it sounds like you're moving more towards an integrative process. So,

that helps me.

The other thing, which I think is very important to include and I did not see in your slides, is your curriculum, your education process for the reviewers doesn't speak at all about the methodology standards and I think those need to be incorporated in the education curriculum as you described it.

MR. DUEÑAS: So, not to put myself on the spot, but we'd be happy to come back and sort of -- training curriculum will be very expensive and then that was just a little sample, but it should include methodology for sure.

CHAIRMAN WASHINGTON: Okay, Christine, I have you, Larry, but these seem to be related.

DR. GOERTZ: Yes, could I just make one point? I mean, I think before we leave this meeting, we have to have better clarity about what it is that we're going to require investigators to do and what we're going to train reviewers to evaluate in regards to the Methodology Report because well, I can tell you it's not clear at all

in my mind where we're at in that continuum, and I just think we have an obligation to our applicants to be just crystal-clear on this and sooner rather than later.

CHAIRMAN WASHINGTON: Okay.

D: Could I jump in a second? That's particularly true in that the response to my question about patient-centeredness, we referred to the Methodology Report.

CHAIRMAN WASHINGTON: Right. So, we're going to ask Dr. Clancy to clarify all of this and she's next.

[Laughter.]

DR. CLANCY: I'm not actually going to clarify that. Carolyn Clancy, Board Member.

Martin, I think that you've had the heroic job of being like where the rubber meets the road here and I think what you're hearing from all of the Board is just how incredibly important this is. So, recognizing that this is sort of dynamic, I can understand that you had your slides in last week, you've made some changes today, which makes sense.

Joe is getting feedback as of probably midnight last night and that's all fine.

I think the fundamental question is, and I'd put this a lot on the Board, I'm not actually sure what problem we think we're solving, and at that end, Martin would have to be a mind reader and a magician.

[Laughter.]

DR. CLANCY: I'm not really clear if we want new ideas, new people, a new culture, or some combination of all of that. If I have gotten grants before and I'm really, really good at this and I'm willing to try some new tricks, is that okay? if I listen to some parts of our conversation, I'm not sure the answer is yes because I think we've got these kind of unbounded aspirations and now we've got someone who's actually to put a system in place, who actually has some boundaries. It has to have some specific steps and so forth.

So, it seems to me that one of the fundamental questions is: How do we use this as a

learning system? And that learning system could have a lot of different outputs. It could shape future announcements. It could shape very important feedback to AHRQ because we get a direct allocation from this trust fund around building capacity.

Now, I have not had any conversations with the Board about this precisely because I didn't want to put any of you on a conflicted position in terms of applying, but with more PCORI staff onboard, that actually changes that equation. We're not accountable to this board or PCORI, but we could actually have a partnership to talk about the kind of capacity that we want to build.

The other thing I would just say is you might ultimately want to think about how do you follow-up with applicants who have not succeeded? We've talked about this a lot in federal land. Sooner or later, it comes down to a survey and you know what happens then. I mean, it's a big burden for us. But PCORI could do that very, very easily. And I think this system has to kind of incorporate

that, but no grants management system can solve the problem of kind of lack of clarity and our ideas and I agree with all of them. I mean, they're all kind of exciting, but they're not all put together. So, Arnie's comment that we're layering different things on top of each other I think is right on and a review process can't solve that for you. If it's not in the announcement and in the clear specs, nobody can do this. So, that's all I'm going to say.

MR. DUEÑAS: Can I say thank you?

[Laughter.]

CHAIRMAN WASHINGTON: Yes. Yes, Martin. And just picking up on Carolyn's point about this is not directed at you, this is part of the process of really just us discussing this since it's on the --

MR. DUEÑAS: I don't take it personally.

CHAIRMAN WASHINGTON: Okay.

MR. DUEÑAS: And I did say 0.25 and I said the more questions, it will give us more clarity.

CHAIRMAN WASHINGTON: Right. Right.

MR. DUEÑAS: So, you're doing exactly what I expected you to do, thank you.

CHAIRMAN WASHINGTON: Okay.

MR. DUEÑAS: And then it'll give me more guidance in creating this system that can provide information that you need to even help out more.

CHAIRMAN WASHINGTON: Right. But in a couple of minutes, we're going to come back to the point that Christine made. So, we're going to leave the table clear about what we mean. And, for now, let's just assume that we're talking about -- because there are these two groups, whether they call them usual suspects, let's call them experienced researchers and the mature, and, yes, we want new ideas from that group, as well, but we don't want it to be limited to just that group, we want to find a way to get the inexperienced researcher, but I see that, but I lay it on Arnie as a separate issue.

So, let's just deal with the first one in terms of we have some experienced investigators around this table, even on the Board who have

looked a little flummoxed by what was being discussed, and so, let's at least clarify. So, let's take off that layer. Some of the suggestions for how we might get to the inexperienced are ones that we can weave in at multiple different points in the process. But for this process, there are a couple of questions that we need to answer very explicitly and I'm going to put them on the table after Debra has commented and then Gail and I guess Rick.

UNIDENTIFIED SPEAKER: And Larry.

CHAIRMAN WASHINGTON: Oh, poor Larry. Debra, then Larry and Gail and Rick. Yes.

DR. BARKSDALE: Okay, I'm only going to ask one question, and this is going to be an easy one. I see on this slide that you had about --

CHAIRMAN WASHINGTON: Your mic, please.

DR. BARKSDALE: It's on. On the slide about patient and stakeholder training, you list a number of things and people have brought up that the Methodology Board is not there, but you also mention other important aspects related to PCORI.

Will this same training or similar training be available to the scientific reviewers, as well as the patient and stakeholder reviewers?

MR. DUEÑAS: You're right, thank you. It's an easy question. So, the training curriculum is going to be for applicants, for reviewers, stakeholders, and everything. So, you just need to be able to -- the material will be the same and we'll have to make sure that we accommodate it for everyone. But yes.

CHAIRMAN WASHINGTON: Okay, Larry, please.

MR. BECKER: All right.

CHAIRMAN WASHINGTON: And then Gail and Rick.

MR. BECKER: The review process that we ultimately select is a really big deal, the engagement of patients and stakeholders is a really big deal, and the training of those patients is really important. So, how are we going to know when we've trained all these folks that we've done it effectively, that they have the knowledge and they have the skills, particularly the patients,

not to be intimidated by the people who have all of the scientific knowledge and so that they can be effective? And because this is a set and you get to do it sort of once this time, yes, they'll be other funding announcements down the road, but it will impact 90-some million dollars. So, how do we make sure they're effective?

MR. DUEÑAS: I was going to say and Dr. Clancy mentioned, this is probably one of the most critical decisions that we need to make and it's important that we produce processes in place that we think is going to give us the output that we need. I wish I can answer that question right now, but part of what we're doing is developing the training curriculum and that there will be measurements in order to be able to gauge whether it's getting what we're getting. So, it's coming.

CHAIRMAN WASHINGTON: Okay, Allen, and then I'm going to lay out -- oh, I'm sorry. It was Gail, Rick.

UNIDENTIFIED SPEAKER: And Rick.

CHAIRMAN WASHINGTON: I'll have to look at

your notes. See, I did fail that chairing course. So, Gail, Rick, and then Allen.

MS. HUNT: Yes, Gail Hunt, board member.

I just think that the PFAs, as they've been written this time, are very clear on what's expected. I say that the last time maybe with the pilots, Pilot Projects, maybe we put expectations on the reviewers that maybe weren't in the actual Pilot Project RFA, but this time I think we're very clear on what's expected and the criteria that we're going to be using. So, I mean, I think that we should go right ahead and do the training based on the criteria and then expect that both the scientific reviewers and the stakeholder reviewers are going to be able to evaluate based on those. So, I don't have problems, I don't have a problem with thinking that we're laying out expectations that they won't be able to meet.

DR. KUNTZ: Rick Kuntz, board member.

I just want to make a comment for the record. I think that we should make some effort to understand how we're going to prioritize exactly

what we've been talking about and almost fundamentally go back to first principles.

When PCORI was started, it was addressing an unmet need, but was the unmet need due to a lack of attention to methods and lack of attention to focus on ways to look at gaps or was it based on the fact that there were usual suspects doing research versus nontraditional people? And I'm kind of a little bit of an advocate for the usual suspects here.

I think that we have a very successful research community in the United States that is based on merit and I think that there are a lot of really good people who spent a lot of time trying to understand these issues and I think we have to basically decide a prioritization and my two cents or vote would be that PCORI has spent a lot of time trying to identify the methodological and focused issues that address the unmet needs in the legislation and that's what we've done for the last year-and-a-half, two years, and that I don't think the main focus was trying to make sure we always

had nontraditional researchers because this is a very complicated methodological process that we're trying to outline and set of standards and we have to take stock in the fact that we have a very accomplished research community in this country.

So, while it sounds nice to be able to say let's get other ideas out there, I want to make sure that we emphasize meritorious applications with basic good understanding of the research aspects first, even if it comes from a place in Boston as opposed to a place -- and that we --

UNIDENNTIFIED SPEAKER: Ask Rick.

[Laughter.]

DR. KUNTZ: And we can be affirmative about trying to get more people involved in the process, but let people know the bar is high.

CHAIRMAN WASHINGTON: Okay, Allen?

DR. DOUMA: I'd just like to follow-up on Larry. I think it's really important that we study the impact of our training, how effective it is. I think we can do it on the fly, we can do, I don't know, it's a two-day training program. The

training ought to be based on, perhaps, some examples of something to review and we can actually test people after they're trained to see how effective it is. And I think we could do it fast enough, particularly we're doing long-distance training, people don't have to be present. We may find that we missed the mark and we can follow-up with a two-hour training session to fill in the blanks. And $90 million is a significant chunk of change and we've got a lot to learn and I think we just focus on that more, including that fact that maybe some board members would like to be trained, as well.

MR. DUEÑAS: I'm taking the training incredibly seriously and it's more than a two-hour that I'm thinking.

DR. DOUMA: No, that was just to make up for -- that's the remedial part of the --

MR. DUEÑAS: Yes. The formalities, I mean, it's not just understanding what we do, but sort of understanding the culture that we're trying to build and we need to understand that ourselves

first before we start training. So, it's very intensive and complex.

CHAIRMAN WASHINGTON: Okay, Rick [off microphone].

DR. KUNTZ: So --

MS. HUNT: Can I --

DR. KUNTZ: Sure, Gail.

MS. HUNT: Sorry. Gail Hunt, Board Member.

Yes, in light of all this discussion that we've had, this is just an idea, but it seems to me like the timing of things is really short so that once we get this PFA out, we're recruiting these stakeholder people, we're training them, going through this whole process, and then we've got this next round that's coming up very quickly, almost too quickly for us to have the opportunity to learn from what happened in this very first one that we're doing, to really learn about what worked and what didn't and how and when. And so, I'm just suggesting that maybe we should have a little more time before we do the next round.

CHAIRMAN WASHINGTON: I think Joe -- well, he can speak for himself and his staff, but see, the next round is part of the same cycle, it's just that we've picked up four of them now and one a month later because we weren't quite ready for it, but it's the same cycle --

MS. HUNT: No, I meant the November.

CHAIRMAN WASHINGTON: Oh, the November. Yes, okay, you can comment on that, yes.

DR. SELBY: You know, I think we've had a pretty strong feeling on the staff that we would like to get into this every four months cycle and we think we can manage it. I do take your point, Gail, and I think that we can play it just a bit by ear. I mean, we have a little bit of time before this announcement would go out in September. By that time, we'll know.

I mean, one of the key things is we don't have any idea how many applications we're going to get, if --

UNIDENTIFIED SPEAKER: A lot.

[Laughter.]

DR. SELBY: We're probably going to get a lot because of the breadth of these announcements, but we'll have a much clearer idea in September, and I would say that postponing it is not off the table if we feel that we could take a couple months and learn a lot more from our first round experience.

CHAIRMAN WASHINGTON: Okay, so, point well taken, Gail.

Here are the two. Ultimately, the question is: Are we comfortable for posting this PFA essentially tomorrow? This week. So, that's the question we're going to come to in just a minute. Weren't expecting a vote, but it may just be are we comfortable? It's not a yes or no. So, that's where we're driving up to.

Picking up on Rick's point, which was going to be really my sort of question number two, but while I may not agree with everything you just said, I just do believe that the point you made regarding where the point where we can learn so much from, we've gone from usual suspects to

experienced investigator to traditional versus nontraditional, and I think that's evolution. But we can learn so much from that group that even as we catch up in terms of educating nontraditional researchers and finding ways to intervene, we shouldn't be worried about that today and I certainly share that view, and my sense from, again, the group is that the group is okay with us not having specific measures in place that will ensure that this is not just organic, but that we are proactively, but that that's the direction that the Board wants the staff to, in fact, pursue and outline for us at some appropriate time. All the specific things we're going to do to proactively find a way to engage and educate, prepare the nontraditional research. So, that sort of takes care of, I think, that tension that I felt at the table. Is that without additional comments, okay?

The second one is a very specific one though. At this point, are we using the Methodology Report as is up on there, are we going to tell reviewers that they are to evaluate the

applications against the standards that are in the Methodology Report? That's a question that we've not answered.

And, Joe, you had one view coming into the meeting and you've --

DR. SELBY: I've had two views just this week.

[Laughter.]

DR. SELBY: I think it's -- you know, I think --

CHAIRMAN WASHINGTON: And Steve is telling me I have to wrap up here. So, okay.

VICE CHAIRMAN LIPSTEIN: [Off microphone.]

CHAIRMAN WASHINGTON: No, no, Steve, solve it for us, please. Yes.

VICE CHAIRMAN LIPSTEIN: Well, I don't know if I can solve this, Rick, but I think you made the point that we shouldn't necessarily divide this into usual versus unusual suspects because of the importance of meritorious and high-rigor research.

But the thing I think we are saying

clearly with this PFA is that the usual suspects should probably not submit usual research applications, that these need to be unusual because if there was an abundance of high-quality, rigorous, patient-centered outcomes research out there, then there wouldn't be a need for PCORI. And because there is a need for PCORI, I think what we're saying is that in this first PFA, you could be usual, you could be unusual, you can be traditional, you can be nontraditional, but your research application needs to comply with a different set of expectations that are outlined in the PFAs and I would argue, Mr. Chairman, that they do need to adhere to the rigorous standards that are in the Methodology Report and it will be available to everybody who's going to be writing their application and it may only be in draft form, but it's good stuff, and so, let's use it.

CHAIRMAN WASHINGTON: Okay, without further comment, I want to get some sense. Call this a straw show of hand. I got this from Kerry. Kerry told me when I don't want to call for a vote,

I can just ask for sort of a straw poll, yes. How many support the view that we need to use these drafts as standard and applications need to be held accountable?

UNIDENTIFIED SPEAKER: To the methods?

CHAIRMAN WASHINGTON: To the methods. Okay, end of discussion. Okay.

So, Joe, do you have any summary comments related to this that you want to add?

DR. SELBY: No, just that this last vote is going to call for a slight modification in the application guidelines, but the Board having weighed in this way, that you're comfortable telling people they should adhere and they're going to be evaluated on draft standards, I think as long as you're comfortable with that, we're very comfortable in putting that into the application and going forward. And, in fact, as Gail knows, that's the way it was until about five days ago.

CHAIRMAN WASHINGTON: Okay, that's --

DR. SELBY: And I want to make sure Sherine also feels comfortable on behalf of the

Methodology Committee with that approach.

DR. GABRIEL: I'm actually happy with it and I'm very happy that the Board weighed in.

CHAIRMAN WASHINGTON: Okay. Since that was not an official vote, it was not official decision.

So, no, Harlan and then Allen.

DR. WEISMAN: I think my sense is that having read the PFAs and read the Methodology Report, they are not inconsistent with each other.

UNIDENTIFIED SPEAKER: That's so true.

DR. WEISMAN: And that the Methodology Report amplifies on things like what do we mean by "patient-centeredness?" I would think it would be very helpful rather than punitive for people to use it because it actually tells people explicitly what we're talking about in the PFA on certain topics. So, I don't think it's a bad thing what the semantics are you must use versus the methods by which you do these things is in the Methodology Report and will be used by reviewers as fine and it is a draft. And we could say although it's a

draft, this points to how to do it.

CHAIRMAN WASHINGTON: Harlan has given us the language. Is your card up or --

DR. KUNTZ: Just a very quick question.

CHAIRMAN WASHINGTON: Okay, you're going to get the last word. Allen and then Rick.

DR. DOUMA: I wanted clarification and then if you just nod at me, then I'll respond. Clarification is are we going to use the Methodology Report as the reference point for patient-centeredness evaluation as well as methods in general? And if that's the case, in looking through the material, which I've been doing the last 30 minutes, it's going to be a significant challenge to train people to be able to use this document in order to review and score our PFAs. Being a challenge doesn't mean we can't do it and we'll turn to you once again, and so, you have no time left at the end of the day. But this is really fairly esoteric, complicated stuff, so, we need to get smart because, essentially, we're training stakeholders in order to evaluate.

CHAIRMAN WASHINGTON: I'm going to ask Sherine, when we were talking about the standards, were we also referring to --

DR. GABRIEL: I was, and I don't have it in front of me, but certainly the goal was far from esoteric. But I think we'll have to look at it and see what areas you have a particular issue with.

DR. DOUMA: Well, it's just the issue is how do you measure the things that are in here?

DR. GABRIEL: Yes.

DR. DOUMA: They're really subjective.

DR. GABRIEL: Yes.

CHAIRMAN WASHINGTON: Well, that could foster some creativity that we currently just can't imagine or have access to. Last comment and then we have to move to the next imperative, which is engaging the patients and stakeholders.

Rick, please.

DR. KUNTZ: Rick Kuntz. I appreciate Steve's comments about this issue about us really focusing on what we want to solve here and I just want to make one more comment, which is you're

right, we might have an issue where people who are more formally trained in research may not have been asking our questions, but, actually, what we measure is what was approved and what was funded, which is a fraction of what was applied. So, it might be an element that a funding agency hasn't focused on those things that we think are important and that actually those questions are being asked by very talented researchers.

So, I just want to reduce a little bit this notion we have to have a wholesale change in the way we do research in the United States and just say what we have here is a great funding agency which is focused on a new set of questions that will reward people to do that and we might see that very talented researchers can ask those questions and answer them.

VICE CHAIRMAN LIPSTEIN: Very talented researchers [off microphone].

[Laughter.]

CHAIRMAN WASHINGTON: Okay. We're going to call this one another very, very valuable and

informative discussion. Thank you, Martin. And, Joe, do you have any comments or we'll wrap this up because, otherwise, I think we have clarity. [Off microphone.]

DR. SELBY: No, I just think this was a very rich discussion that gave us modestly-changed way forward, but something we can handle and very appreciative and I think improved, better.

CHAIRMAN WASHINGTON: Okay, great. Just looking ahead doing a time check, we will honor our public comments period, which is scheduled from 3:15 to 3:45. Right now, we only have a couple of individuals who have signed-up. And so, my thought is that we would go to -- I think we need about a 10-minute break. So, we would go to 3:05 and take a 10-minute break and then start the public comment period and anything that we have to continue related to engaging -- we can continue during the public comment period while we're waiting if somebody else comes on. Does that seem reasonable? So, essentially, you have about 25 minutes and then we'll continue. Okay.

DR. SELBY: So, 25 now and --

CHAIRMAN WASHINGTON: Twenty-five now, and then we'll continue.

DR. SELBY: Okay. So, I'm going to turn this over to Anne in a second, but I just wanted to mark that this is the first time that we've spoken with you about beginning to set up a more formal structure for the way that PCORI engages with the entire community, patient and patient advocates and caregivers and all of the people that we hold important as stakeholders.

This is important because I think in addition to us reaching out when we feel compelled to talk to individuals or to invite them to come to meetings, we need to have channels for people to reach us, we need to have channels for people to get their ideas to us and ultimately, we need to have patients and stakeholders to sit on our work groups and our advisory panels and to help us refine the Research Agenda.

So, Anne and Judy and Susan and Sue, who's not up here at the table, have all been working

hard both in refining the operational plan that flows from the strategic plan and getting this presentation in order and our plan, it's parts of it are already underway, but we really want to get your reaction and your suggestions. This is a time for a rich discussion, including your ideas. All of you represent stakeholders and you can all help us think about how to do this effectively and efficiently.

So, Anne, I'll turn it over to you.

DR. BEAL: Good afternoon. So, as Joe said, and you might have heard him say this earlier this year, but we in many ways think about 2012 as being the year of engagement, and so, when you think about the fact that we now have our Funding Announcements, we have our national priorities, and the question is: Given where PCORI is, how is that we're going to engage key audiences in the work that we're doing, as well as what is it that we're going to engage them in? So, what you're going to hear today is a little bit about our plans for both the patient engagement work, as well as what we're

calling our non-patient or stakeholder engagement work.

But before we jump in, I just want to really take a moment to talk about why do we engage? Why do we engage with these different audiences and really what is the goal that we're trying to achieve?

So, when you think about PCORI and what it is that we do as a research enterprise, there are essentially four things that we're interested in doing. One, as a research enterprise, we're interested in asking meaningful research questions, and so, we've heard a lot in terms of today's discussion about making sure that the questions that we ask are really meaningful and relevant to both clinicians and patients and their caregivers. And so, part of the engagement process that we're very interested in participating in is really making sure that we are asking the right questions.

One of the things that we've now started to talk about is really moving forward, trying to develop advisory groups to get to this issue of

specificity that we were talking about earlier today. And so, in some of our preliminary conversations, we've been talking about advisory groups that are related to the five areas in our National Priorities as well as potentially advisory groups related to rare diseases, advisory groups related to RCTs, Randomized Control Trials. And so, when you think about the process of really getting to prioritization, it would be very important for us to engage the field and in terms of these advisory groups, as well as in terms of other activities that we'll be engaging in.

The second thing which you heard a lot from Martin's presentation is that we're also going to be engaging stakeholders in both the review of research and in the conduct of research. So, it's not just asking the questions, but when you're trying to answer the questions, are people really fully engaged as partners?

And then, ultimately, once you have the questions, you answered the questions, then you need to think about how do we get it out there?

How do we get it out to the right audiences? How do we make sure that people have it in the form that really works for them? How are we answering the questions that are most meaningful to them? And so, we're really thinking about this as we go forward and are really thinking about dissemination of our work. We want to hear about this from different stakeholders to really understand what is it that are their needs and their priorities to get this information out?

And then, lastly, when you think about the fact that we've talked quite frequently about our desire to be a learning organization, one of the things that we want to say is, are we having a desired impact? So, we've talked a lot about impact in terms of our review process, but as an organization, are we having the desire to impact that we want to have on the field?

And so, obviously, it would be patients and the other stakeholders who will be able to answer that question best, and so, we plan to engage them very robustly in terms of really

telling us are we doing a good job?

So, just very briefly, what we've done is really taken a moment to really define who are some of the stakeholders that are key audiences for us and I think that's actually a very useful exercise. We've actually been having these conversations internally. We've also been asking question to the COEC to really make sure that as we think about who it is that we're trying to reach that we really have a good understanding as to who the key target audiences are.

And we actually were very pleased when we recently saw an article written by Concannon that was published in *J. Gen.* that really talked about this new taxonomy for stakeholder engagement and patient-centered outcomes research and found that much of our thinking was very similar to the thinking that was mapped out in this article. So, we just wanted to highlight this, and, in fact, there are copies available of this article outside, but just wanted to really make it evident that there are others who are also thinking about it,

and so, this is very foundational work for what it is that we're doing.

So, with that said, I'll now turn it over to Judy Glanz, who's going to talk about our plans for patient engagement and then you're going to hear from Susan Hildebrandt, who will talk about our plans for non-patient stakeholder engagement, and then we have a series of questions that we're going to present to you to really help us with our thinking and refinement of this plan.

MS. GLANZ: Thank you. Hey, everybody, I'm very happy to be here. Can you hear me?

DR. BEAL: It's on.

MS. GLANZ: Now, I am still very happy to be here and to tell you a little bit about what we're doing, some of our activities in patient engagement, and I think the conversation that we've been having here all day actually sets a very nice frame, and with any luck, I'll be able to address or even answer some questions you've asked, but I'm sure you'll let me know whether I've succeeded.

I think I want to start by saying that

genuine and robust patient engagement in every aspect of our research enterprise is a major differentiator for PCORI, and I think we're all thrilled about that and very excited about what that can mean for us. And I defer to our most inspirational speaker, Dr. Krumholz, but many of you will remember that at our stakeholder dialogue last February, he talked about that if we do get it right and if we do invite patients and caregivers to share their wisdom and guide us, that we are given an unprecedented opportunity to turn the research paradigm upside-down, and I think that guides many of us in what we do here each day.

So, let me see if I can work this. This is the guiding us part. Okay.

Now, I want to take one moment to tell you something about who we're talking about during this presentation, and I'm actually going to sidestep some of the formal definitions and just tell you that for the purposes of this conversation, I want to say that caregivers and patients are really all of us. They're who we have been, who we are now,

or who we will be. They're parents, they're children, they're loved ones, brothers, sisters, they're really all of us and I know there are some complex definitional challenges, but that's where I think we can keep it for now.

And the statute directs us and we also want to give particular attention to a variety of subpopulations, and that includes racial and ethnic minorities, women, children, seniors, those with comorbidities, those with rare diseases, people with disabilities, and we want to work with these populations to eliminate their barriers to participating in our work and also to be certain that the questions and the evidence gaps that involve them are addressed. And I'll delve into that a little bit more as we go forward.

So, the presentation outline, I'm going to start by telling you something about some of our engagement activities and a timeline for those activities that will take us through to our next board meeting in September, and then I'm going to suggest some of the activities and processes around

which we may want to measure our success, see if you think they're on target, and then after Susan and I do our presentations, Dr. Beal will wrap this up with a series of questions that she'll pose to the Board. And, as I said, I'm sure you'll have questions, as well.

So, to reiterate what Dr. Beal just said, how are we going to do this? Well, we'll going to do our process by making sure they're asking meaningful questions, we're going to look to patients and caregivers to guide us in the selections of the questions that are relevant to them, and then we're going to invite them to be a part of conducting the research itself. There's been a lot of discussion here today about being a part of the review process, and we are putting various mechanisms in place just to ensure that patients and caregivers are equal partners in both the conduct of the research and in the research review. And it will be key to involve these same groups.

I asked Gail if I could speak about

caregivers because I have to keep saying patients and caregivers, but we're not sure that's going to work. So, we're going to work with patients and caregivers to disseminate the research findings and we're hoping that will also accelerate getting the research out into the field by having so closely involved both groups in the process.

Ultimately, we're going to ask if we're doing a good job, as Anne said. We're going to find out if we're asking the right questions and we're going to do this continuously and regularly because we're constantly going to be looking for that feedback.

So, before I talk about how we're going to generate topics, I just want to underscore some of the things that I heard around the table today, too, about we have to start this entire process by building trust with the communities in which we're going to engage. Leah talked earlier about sort of walk in my shoes. I heard Gray talk about getting to the communities, talking with people directly. Others made similar comments, and I think that all

of our work is predicated on building this trust and listening carefully, and as the title of the presentation says, to really and truly be guided by what patients and caregivers want us to understand.

So, at this point, we're working, and I think that Martin referenced that we're working now to determine the best methods for topic generation. We're getting very critical input from the Methodology Committee, from ARHQ, from others who have been in this arena.

Once we decide how we're going to generate topics, and this is a question and we need some uniform approaches, we're going to solicit them in a variety of settings. We're going to do this online, we're going to conduct surveys, there are very vibrant e-patient communities, we're going to work closely with existing caregiver and patient advocacy organizations, we're certainly going to leverage the resources and the contacts of our board and our Methodology Committee, COEC, different folks in the room, and we're going to work also through community-based networks and

community health clinics and we're going to look for trusted organizations and individuals in the community as a way to accelerate the process of building trust.

And we're going to go outside of Washington because many of the folks that we need to talk to are real people on the ground who are not represented by organizations and who are not professional patients and have to be brought along in special ways. This also addresses some of our commitment to addressing disparities.

We've actually set up a workshop plan, which we won't have time, I think, to talk about at great length now, where we've created a plan of infrastructure for going out into communities. We're doing our first workshop, coincidentally, in Boise, where Sue Sheridan is based, and we'll be looking at a number of special populations there, including Native Americans, Latinos and Asians and the list goes on and on, and some of what we're talking about in terms of building trust in communities because Sue lives in this community,

has some of the context that will really sort of accelerate the process and will give us a model initiative to look to use in other places.

Once we have on an ongoing basis generated the questions, we're going to build on the work with the Methodology Committee and the work of AHRQ and other specialists and convene a workshop to develop a framework for PCORI for the prioritization process. It's very important to us that in this process we commit to establishing a credible, transparent, multi-stakeholder process in which patients and caregivers are equal partners. My job is to always make sure that these folks are equal partners and Sue works hardly with me to do that.

We're going to do this through, as several people have mentioned, a series of advisory panels, workshops, and other multi-stakeholder approaches, and we know that we are going to need to provide extra support and extra skills-based capacity-building to some of our patients and caregivers so that they, in fact, can participate as equal

partners in these various structures.

In the second phase, we're going to involve patients and caregivers in the conduct of the research itself and we're going to start by asking them to assist us in selecting the research that PCORI will fund. I know a lot of you had questions about this. I want to say that we have done some evaluation of the pilot funding that will help inform us as we do the recruitment for this next round.

So, I need to move along. We're going to train and recruit patient and caregivers to review the funding in a variety of ways. We're going to do this again through online call for reviewers, through patient caregiver organizations, through the resources of the Board, and through AHRQ and others, and this we're working on right now. Martin and several of us are working on actually developing the online call for reviewers and we're trying to do this in a very accessible way so that nontraditional patients and caregivers will feel welcome and want to be a part of this review

process.

Then we're going to take a look around. We're doing a landscape review now to see what are some of the best practices in research reviewer training, and, ultimately, what we want to do and we will have in place for this next round is our own PCORI Research Review Training Program, and because we need to accelerate this because we're sort of behind the eight ball, we're also going to be looking at groups who have already trained research reviewers, the Department of Defense, the FDA, the Breast Cancer Coalition, a number of folks who we can then accelerate through this screen of PCORI Training Program.

I'm very excited for all of us, I think, is that we really do have a chance to shift the paradigm in significant ways in that we are going to require for successful PCORI research applications, we'll require a robust, comprehensive plan for engaging patients and caregivers, and that will be in every phase of the research, in the design, the conduct, the dissemination, the

evaluation, and in the uptake.

So, in the third phase of our four phases of the process for engaging patients and caregivers, we're going to work closely with both groups to make sure that the research findings and the evidence is disseminated. We're going to look to organizations that have pathways, channels within their own membership, perhaps online, and we're going to be looking for new channels.

There was a great mention in here about novel collaborations. We're going to look for novel ways to get the dissemination and the findings out there just as that we're going to look for novel ways to ask the questions and to conduct the research itself. There's been some discussion about potentially soliciting kinds of research or setting aside for incubation projects. I think all of those things are on the table.

And we'll also be working with those patient and caregiver organizations that have special capacity to reach priority populations with this new evidence for decision-making and through

online networks and other sources. We want to get to those populations. And I think we all believe that by involving patient and caregivers in every part of this work, that we will then create incentives to accelerate the dissemination of research, which is basically hoping that we create a milieu which patient and caregivers are going to demand this evidence because of their engagement in the process.

So, finally, as I said earlier, I'm trying to hurry here. So, we've got the evidence to patients. As has also been discussed here, we have a feedback mechanism. We want to understand if we're doing a good job. We'll be going to patient and caregivers regularly and we'll revise and refine our work based on what we hear from them. We're going to want to know if our material is understandable, are the training materials effective, are folks satisfied with the level of participation? We realize that we have challenges around health literacy and numeracy and we're going to see if we can address those things effectively.

Let me just take you very quickly. This is our plan that will take us through to the next board meeting, and there are just a couple of things in this plan that I'll call out for you.

One of them is the workshop that we're planning in Boise, which the timelines move a little bit, but we will get it done sometime this summer. We're going to have a heavy lift, as has been discussed here, to get the reviewers up and trained and to bring a sufficient supply or patient and caregivers and we'll be working on that through the summer so that we'll be able to do training in September and October.

We're planning several roundtables at this moment. One is with the disability community. We're looking at how to work with NORD and to bring around the table several folks from the rare disease community. Sue and I met yesterday with Gail Hunt to talk about a fall meeting of caregivers and the list goes on and on. So, that will quickly take you through those two slides.

So, finally, what we're going to do is

we're looking at a structure process outcomes tool to try to look at aspects of our work that we may want to measure our success against. I think we're focused especially in the process part of this, and these are issues around outreach, making sure that we've reached the right folks, have we created the right partnerships, and that includes novel partnerships, great commitment to that. Have we gotten the right people on the right advisory committees and other working groups? Do they have the capacity they need? How can we facilitate that on an ongoing basis?

And after my presentation and Susan's presentation, Anne is going to take us back around to see whether you think these are the right elements that we should be measuring and suggestions for other things we might want to look at, as well.

CHAIRMAN WASHINGTON: Okay. I'd like to open it up first for questions for Judith, and I want to remind you, your time is not going to be cut short.

MS. HILDEBRANDT: In half.

CHAIRMAN WASHINGTON: Well, not in half. It's going to be two pieces. You don't have to just rush through things. Well, are there question related to this because there's quite a bit that you put out there? And so, I'm going to start with one question.

I understand the fact that we're going to study what the PCORI Methods Report outlines in terms of maybe original reports, but what I didn't hear and maybe it's there is that we're going to somehow through these activities ultimately help define some specific research questions that get at this very issue of how do we, one, engage patients and, two, how do we solicit questions?

Sort of each one of the ones that you've raised ultimately, we want to be the leaders in conducting the rigorous research that answers those questions, and while we can start qualitatively, which is a great place to start, I don't think anyone on the Board wants that to be the end. And, so --

MS. GLANZ: I think Rachael Fleurence talked about this a little bit this morning, and we're lucky to have expertise onboard that will help us to create this process and I think much of what we are doing now is qualitative. We are meeting one-on-one in small groups and we're collecting information, but we do need a uniformed kind of process and this is something that's very much going on right now to put that process together. And, for example, when we go to Boise, we hope we'll actually have a tool in place. Not that we'll go in with white lab coats, but that we'll have a sense of the way we want to get information. And a lot of that is translating through patient narratives, patient stories; it's not going to come to us just the way we want to digest it.

CHAIRMAN WASHINGTON: Right.

MS. GLANZ: But we do need a process. I'm not sure I answered your question.

CHAIRMAN WASHINGTON: Right, not exactly, but this is helpful and we have to start where

we're starting, and in some cases, the qualitative measures is going to answer the question. But I'm suggesting that I'm thinking the work that you are doing to engage stakeholders and patients is a part of the ongoing work of PCOR, which is conducting Patient-Centered Outcomes Research, so, it's a research group and it's got to be a channel that automatically is going to feed that to that group. It's the same with the methods group. And so, I don't know if that's going to come from Anne or whomever, but I'm saying this is an activity within this imperative without some acknowledgement that it's got to flow over to these other two groups, and that's what's missing for me right now.

DR. BEAL: So, Gene, you hit the nail right on the head. So, as we think about the plans even for the Methodology Report and the public comment period, obviously, one of the things that we'll be doing is reaching out to lay and patient audiences to really ask about the engagement component about it in particular. So, while we have plans for having them focus on that, we also

have plans for having them focus on the entire report, as well.

And then the other thing, which I mentioned briefly at the beginning, were the advisory committees, which is really helping with the Research Agenda. So, we really view that as coming onboard early on.

CHAIRMAN WASHINGTON: Right. We have Gail, Larry, and Sharon.

MS. HUNT: Gail Hunt, Board.

Could you talk a little bit more about this physician survey and why just physicians and what are you expecting to collect from physicians?

MS. GLANZ: Well, first of all, I'm going to let Susan Hildebrandt handle that question, as she talks more about clinicians, and I think the notion of surveys in general is to collect some baseline data to see against which we can measure progress along the way. But when Susan speaks, I'll let her speak to that.

MS. HUNT: Okay, but what I was asking was I understand the concept of baseline data, but, I

mean, I'm wondering if it's like these focus groups that we did where we asked people of these five areas that PCROI is interested in for research, what do you think is the most? And the people really had no idea. So, if this is like just asking physicians do you know what PCORI is? Have you ever heard of PCORI? Well, we know from Ellen that there are some anyway who haven't and probably most haven't. So, it needs to be something that's really valuable to us at this point.

MS. GLANZ: Juncture, right.

MS. HUNT: Yes.

MS. GLANZ: Again, let me just speak in the context that I am doing my work in of patients and caregivers. I said earlier that I think building awareness in the community in a sense that we are out there to do something that's helpful is the first thing we have to do because to go out with a set of surveys that aren't meaningful aren't meaningful. So, I think, again, to demonstrate value to sort of define ourselves I think is a baseline in the communities that we go to. Gray

and, again, various folks around the table have talked to -- and Ellen has talked about her cousin in upstate New York. Lots of folks don't know anything who we are and don't understand why we would have any value to them. So, some of these questions aren't meaningful until we sort of percolate out more understanding of what we're trying to do in the patient and caregiver realm.

CHAIRMAN WASHINGTON: Larry and then Sharon and then we're going to break.

MR. BECKER: Well, then come to upstate New York.

[Laughter.]

MS. GLANZ: Happy to do so.

MR. BECKER: So, this is incredibly important and complicated and I would just add one more challenge. There's a great deal of focus here on the input side and I want to challenge you to think about the output side as you engage these patients so that after they've given the input, after they've helped decide which research is done, there's a dissemination and communications

challenge and to think about as you structure this how can you best utilize those people on the output side, on the communications and dissemination side of this task.

MS. GLANZ: It's critically important and I think having worked in the engagement realm for a long time, I think you need to reflect back that you've folks in ways that are demonstrable and I think the only success you'll have is engaging them in the dissemination and uptake of the work. Otherwise it's for not really.

CHAIRMAN WASHINGTON: Okay, Sharon and then we're going to break.

DR. LEVINE: And this is really around the issue that Gene raised around connection. So, for example, under "Accelerate dissemination," there's no mention of AHRQ.

MS. GLANZ: I apologize. AHRQ is key of that and it was an oversight.

DR. LEVINE: And so, my plea is that you've listed a tremendous number of activities and every one of which in its own right may be

valuable. They need to tie together into a whole and they need to tie together with the rest of the work. And so, in terms of dissemination, we have a lot of work to do to understand as we build connections how AHRQ's carrying out its responsibility for disseminating PCORI research, frees us up to think about what else we can do that's value added and duplicative. And in the same way --

MS. GLANZ: It's very important.

DR. LEVINE: I think certainly the Dissemination Workgroup and the COEC is going to need to see a work plan around this work where we understand when we're going to see what we're going to see, what kind of input and involvement, and I appreciate the distinction that's been made in the document, that's helpful for me, where you're going to want input. Well, we're going to want involvement. So, again, this is a very ambitious timeframe. We need to be able to plan our work as board committees to ensure that we aren't the chokepoint, if you will, for getting the work done.

MS. GLANZ: That makes complete sense. We actually have a fairly drilled-down, detailed work plan that we're happy to share with you. We have not shared some of this with you yet, yes.

DR. LEVINE: Again, that's great that you share it with us. The question is: Do you want input or do you want involvement? And to the extent that we have work to do, we need to ensure that we actually have as a committee or as committees a meeting schedule and enough time to actually do the work.

MS. GLANZ: All of that makes perfect sense and I understand that we need to give you discreet places where we're looking for input and feedback and we'll work to make that much clearer.

DR. LEVINE: Okay.

CHAIRMAN WASHINGTON: Okay, thank you.

Joe has a couple of comments to add and before I get to Joe, Judy, what you're hearing is that you now have our attention. Okay.

[Laughter.]

MS. GLANZ: I can see that.

CHAIRMAN WASHINGTON: And while this is, indeed, foundational, we're not being critical; the truth is, we've been focused on so many things and we're excited and eager to be involved in this to support you and move this forward, and I like the way that Anne captured it. You can think of the rest of 2012 as the year of engagement. And so, you're going to have our attention.

DR. SELBY: [Off microphone] -- engaged.

CHAIRMAN WASHINGTON: Yes, we are engaged.

MS. GLANZ: We think of it as the year of very little vacation.

CHAIRMAN WASHINGTON: Okay, Joe, last comment.

DR. SELBY: This is a small comment and it's only one and it's to the point that Sharon made about involving AHRQ, we had mentioned dissemination, and it's actually a lesson I learned from the Dissemination Workgroup who sent us suggestions for Dissemination and Implementation Plan and several of the items that went into our Dissemination and Implementation Plan were who are

you engaged with? Who have you put on the Research Team, what kind of organizations are you working with as you do the research, and it's just that notion that to the extent that you engage patients and clinicians, obviously, in asking the questions, prioritizing the questions, following the research with you, you have hopefully, at least theoretically, a kind of built-in dissemination opportunity there which might not take a massive dissemination effort onto itself once the result -- probably both are going to be essential.

But I think when Judy's talking about dissemination. She's talking more about that organic kind of dissemination which flows from not popping research findings on people after the fact.

CHAIRMAN WASHINGTON: Okay. So, with that, we're going to take a break and actually, it's 3:06. So, let's take a 14-minute break.

[Laughter.]

CHAIRMAN WASHINGTON: So, I think our public participants will allow us five minutes. So, we're back at 3:20 for the public comment

period and then we'll continue. Thanks, everyone.

[Recess.]

CHAIRMAN WASHINGTON: Welcome back to the next session of the Board of Governors' Meeting for PCORI, and during this period, we're going to hear from the public and here to introduce this session is Mr. Josh Reese [phonetic] So, Josh?

MR. REESE: Great, thank you. Just a couple of quick notes on the guidelines before we get started. Individuals offering public comment should limit their remarks to no more than three minutes and any written testimony can be submitted to PCORI via e-mail at info@PCORI.org.

I'm going to call our first public commenter and that'll be Kerri Diamant.

MS. DIAMANT: Hello, Eugene and Board of Governors. Thank you for inviting me here today. I'm the executive director and founder of a local non-profit located in Fort Collins, Colorado. It's called AlterMed Research Foundation and I started the foundation because I witnessed my mother dying of cancer and I saw the limits to chemo and

radiation.

And so, I thought to myself coming to Taiwan, with a different health philosophy, when she was dying, I was looking for acupuncture for her and I felt talking to the oncologist, I was not very well supported and I wanted the conventional medical industry to be more supportive. Today, as you know, patients are very savvy on the Internet and conventional medicine is very good with acute diseases, but when we're talking about chronic illness and cancer, we are talking about something that the conventional research community has been looking at for a long time and not able to solve. And so, I think as this group, we have a wonderful opportunity to make a difference in that someday our loved ones, our relatives will not have to face cancer or chronic illness.

And so, if you look at federal dollars, 99 percent of the research dollars is going to conventional medicine and less than 1 percent is going to complementary, alternative medicine. So, if researchers are applying to NCCAM, maybe 10

percent of the researchers will get that small amount of money.

Well, anyway, so, I think if you look the two populations, you've got the conventional medicine people and you got the holistic health people, and sometimes, they kind of use one and if conventional medicine doesn't work and we're looking for hope, then we're looking to holistic health or people who are not struggling with cancer or chronic illness, they are looking to holistic health to prevent illness. And so, you're looking at a growing market, people going to Whole Foods, natural grocers. So, 40 percent of Americans are using complementary alternative medicine and sometimes because they don't like the side effects of conventional medicine.

Like, for example, with eczema, personally, I don't want to use prednisone because I don't want to maybe gain weight, but I would like the research community to help me go to root cause. And I agree, root cause is not so easy to do. Okay, sometimes, we back off because something is

hard to do. We've got to back off on curing cancer because it's not so easy. So, we settle for less. But this group, I mean, I see you guys are very bright and I have a lot of hope. I'm really excited that it's patient-centered.

So, I guess what I want to say is I would encourage that you look at I'd say complementary and alternative medicine funding because we're not talking about people of color that we need fund more health care reform to people like me, but we're looking at a fundamental health care change in that we're looking at people who are going green, people who care about nature, people who are into holistic health, and so, it's a change in paradigm shift.

And so, when we're looking at untraditional population, I think that I appreciate you're looking at disparities, but please also look at, today, our medicine is about sick care and we're really looking at how do we focus on prevention and wellness. So, that means holistic health and complementary and alternative medicine,

and being Chinese, I'm not asking people to speak Chinese. And so, what I'm saying, I'm for holistic health. I'm not saying lower the research bar for complementary, alternative medicine. In fact, I think the gold standard, evidence-based research, I think CER is very great. I think it's great that NCCAM and NIH, they're focusing on mechanisms, biology, and you guys are focusing on CER. I think that's wonderful and I've seen a lot of great work that you presented this morning and I'm really encouraged.

So, I'm just wanting that more dollars go to complementary and alternative medicine because, today, we've got Baby Boomers reaching retirement age and we have chronic illness and cancer that we have to solve. So, please look at a new paradigm.

And then another thing is when I was going through seeing my mom dying of colon cancer, I wanted people to help me sort the wheat from the chaff. I was an engineer, but I was looking on the Internet, I was looking for hope. And so, what I'm saying is yes, this group will help me sort the

wheat from the chaff, but my patient values are a little bit different in that if I have cancer, yes, if chemo and radiation have high effectiveness, I would use that. If I have chronic illness and if conventional medicine would solve my problem, I'm all for it, but if not, chronic illness, if I have that, my philosophies are I use surgery and I use pharmaceutical drugs as the last resort. So, not all patients are the same and you got 40 percent who prefer holistic health. So, when you're saying you're helping patients to sort the wheat from the chaff, please remember patient values.

And then a couple of other things. When you're talking about research methodology, I'm really encouraged by that and I think a couple of things. When you talk to holistic health professionals, I think that there are two things that they have a gripe about. One is that it doesn't go into root cause. So, when I have tendonitis or something, I prefer somebody finds out is it ergonomics? Am I not sitting properly with my posture instead of giving me pain

medication. How do we just address pain? And so, one thing is looking at root cause.

And one thing I want to encourage you to do is like the automotive industry, where we had Edwards Deming brought in root causes analysis, that is what is being done in engineering industry and being an engineer myself, I understand the body is complicated, we can go to root cause, but I would encourage that we look at multi disciplines, bringing in engineers to look at health to say how do we go to root cause?

I understand the body, it's very expensive, but we should look at root cause because back pain, some people, the problem is posture, some people it's psychological. I mean, we can't use the same treatment for everyone. So, everybody's unique, but federal dollars, health care is a very personal thing. So, we should make sure that different patients, they are treated according to their values and be treated according to their causes. So, I would encourage better diagnostic criteria as part of the root cause

analysis.

And then the second one with regard to research, the pet peeve from the holistic health community is that we're not looking at the whole person. So, as you know, conventional medicine is very much about reductionism, it's very much looking at body parts, but we are made of mind, body, and spirit, and so, what happens is we are looking at multi variables and that's very expensive to do, so, what we do is we settle, we settle for randomized control trials with just one variable. Well, we've got computers. I mean, in 2029 with singularity, computers are going to surpass human intelligence and I don't see why we can't use super computers to look at the various variables to solve some of these health problems.

So, I would say maybe by then let's cure cancer and chronic illness for everyone.

CHAIRMAN WASHINGTON: Thank you, Ms. Diamant.

MR. REESE: Our next commenter will be Tami Ellison.

MS. ELLISON: Hi. I want to thank everyone today. It was really very interesting, I have to tell you. I am a patient. I was gone for two hours, so, I apologize. I had to go see the dentist.

[Laughter.]

MS. ELLISON: I am also a former research scientist and I have worked in the clinical environment. And in the interest of transparency, I am a government consultant, as well.

So, I guess one of the concerns that I actually had is that in separating the wheat from the chaff accordingly, there's also a population of patient stakeholders. Those are groups that are already engaged in grassroots movements, those who are involved with whether it’s a chronic or an acute illness or an orphan disease. So, in being able to reach out really down into the weeds of patients, and I consider myself a stakeholder on many levels and I think all of us here should, as well, which was something that was brought up before.

So, I guess that, to me, is a bit of a challenge in terms of how you accomplish that and you said some very ambitious goals, wonderful goals, I have to tell you. One thing, however, patient-centered outcomes doesn't mean a lot to me and I'm a scientist. And I'm not sure it actually means a lot to people. So, in looking over your mission statement and thank you for letting me look at it, as well, one of the things that I noticed in there is that it doesn't say just towards better health outcomes, it's what is defined by the patient, and from a sociological or cultural standpoint, that isn't necessarily the best that medicine has to offer. So, it's a very subjective sort of approach.

So, I was just kind of curious in terms of that really it's just a comment to congratulate you on what you're doing and I do wish the best in that, but getting to the root of it, you have a lot of different inputs, a lot of different outputs, whether it's patients, caregivers, doctors, and how you overcome that paternalistic type of environment

that has notoriously plagued us.

CHAIRMAN WASHINGTON: Thank you, Ms. Ellison.

MS. ELLISON: Sure.

MR. REESE: Our next public commenter will be Lauren Frey.

DR. FREY: Hi, everyone. Thank you for this opportunity to make my comments. My name is Dr. Lauren Frey, I'm a physician. I subspecialize in the care of patients with epilepsy and I see patients both at the University of Colorado Hospital in the Neuroscientist Center as well in the Epilepsy Monitoring Unit at the University of Colorado Hospital. I'm also the assistant director of the Epilepsy Monitoring Unit and an active participant in the Epilepsy Surgery Program at the University of Colorado Hospital.

The Epilepsy Surgery Team is a multidisciplinary group of neurologists, neurosurgeons, radiologists, and psychologists who evaluate and direct surgical intervention for the treatment of refractory epilepsy. My interest in

the institute stems from my medical practice, where I focus on the processes of the development of epilepsy after traumatic brain injury. About 20 percent of people who survives severe traumatic brain injury will develop epilepsy. Developing tools to predict which survivors will develop epilepsy will allow physicians to identify and aggressively treat TBI survivors that are at the highest risk of developing seizures in hopes of preventing their epilepsy altogether.

As a local physician and an active member of the Epilepsy Foundation, I know that the institute is an important group. I speak to you today to share concerns from Epilepsy Foundation about the process by which this institute establishes its research priorities and research agenda, as well as share an example of comparative research in a process that we feel has missed the mark in serving both patients and providers.

For the institute, the broad teams that have been chosen by the Board seem to be consistent with the institute's authorizing statute. However,

the foundation questions the process by which the individual projects are chosen. As established, it appear that the institute would have the Board choosing research topics as part of the agenda-setting process as opposed to the process used by the NIH or the AHRQ as they solicit grant applications from the research community. It is not clear to me as a practicing physician and epilepsy researcher how the institute's process for selecting research topics is different from these existing governmental programs. It is the distinction from the governmental programs that led many patient groups and certainly the Epilepsy Foundation to support the creation of this institute.

As an example of what patient organizations would like to see improved, the Epilepsy Foundation submitted comments and key expert recommendations for a report on anti-epileptic medications to the agency for health care research and quality. This AHRQ report started from very broad, key questions that the foundation

along with other epilepsy patient and provider organizations strongly questioned for their value to both patients and providers.

Despite this, however, the report moved forward and while some of the experts recommended reutilize by the lead researcher, they were not consulted or engaged in a valuable manner. There was no overall discussion of the research project, no interaction between experts, and no feedback or discussion among the group. In essence, this group of key informants how appeared to endorse this report had no input in the drafting, discussion, conclusion, or recommendations. This is not an example of valuable engagement. While independence and non-bias are important, they should not take precedence over involving the key patient, research, and provider organizations in a discussion and analysis of research and clinical recommendations.

I am looking forward to seeing this institute evolve from making competitive research grants to an institute that selects research topics

and contracts for the conduct of research and engages patient and provider organizations and lead experts in an effective manner. I understand that the institute is concerned about leaving out certain diseases from its research, but in the end, only certain topics will be funded and the question here is simply who makes those decisions?

I would argue that the topics selected by the institute for research will have more credibility if the selection comes from you, the stakeholder board, in an open and transparent process as opposed to a closed-door, NIH-like review process. I applaud the institute's efforts to engage individual patients and practitioners around the country. I would also urge you to tap the vast resources and knowledge of professional and patient associations.

Although I'm happy to engage directly with the institution as an individual physician, it is often through my professional associations that I vet my views and concerns about research and policies that are affecting the health care system.

As I mentioned before, I'm a member of the Epilepsy Foundation, which was a strong supporter of the establishment of the institute. I think that they are representative of the views of physicians like me and of the views of my patients. As such, they can be effective conduits for broad stakeholder engagement. I hope that our home office will be afforded the opportunity to meet directly with patient, stakeholder, and communication staff here at the institute. I also wanted to share the message that our organization also hopes that the stakeholder engagement staff will find the time to meet with two of the larger patient and disability coalitions that exist currently, the National Health Council and the Consortium for Citizens with Disabilities sometime in the near future.

In closing, I appreciate the opportunity to comment and please know that I would welcome any opportunity to further discuss the research needs in the epilepsy community or even to serve the institute in some fashion. Thank you.

CHAIRMAN WASHINGTON: Thank you, Dr. Frey, and your suggestion reminded me to emphasize to all of our speakers, if you have something written to share, please do because we do look forward to following up.

MR. REESE: Thanks. I'd now like to check in with our operator, Carla, to see if we have any individuals wishing to comment by phone.

OPERATOR: If you would like to make a comment, please press star then the number one on your telephone keypad. Again, that's star one on your telephone keypad to make a comment. And we have no one in queue to comment at this time.

MR. REESE: Thank you, and now I'd like to open it up to anyone in the room who is wishing to provide comment at this time.

[No response.]

MR. REESE: Thank you.

CHAIRMAN WASHINGTON: Well, you didn't give them much time to think about it, Josh.

[Laughter.]

CHAIRMAN WASHINGTON: We'll give them a

couple of minutes. I don't want staff jumping up in disguise though.

[Laughter.]

CHAIRMAN WASHINGTON: Well, Josh, for the next ten minutes, in order to honor the entire period, while we're going to proceed, if someone approaches you, let us know.

MR. REESE: Great, thank you.

CHAIRMAN WASHINGTON: Okay, and thank you very much.

Okay, Anne, I think you need to just refresh our memory of where we are and introduce Susan.

DR. BEAL: So, we are in Denver.

[Laughter.]

UNIDENTIFIED SPEAKER: Thank you, Anne.

CHAIRMAN WASHINGTON: I asked for that one, okay.

DR. BEAL: Not that I'm concrete in my thinking, I'm sitting next to the psychiatrist.

CHAIRMAN WASHINGTON: That's a good one.

DR. BEAL: Okay. So, just to remind this

group, we are going to now hear from Susan Hildebrandt on our plans for stakeholder engagement, and then as I said, we have some questions that we will pose to you after you had a chance to ask questions of us.

MS. HILDEBRANDT: Great, thank you. Hi, I, of course, am delighted to be here to talk about our stakeholder engagement plan. As Anne indicated earlier, I will be speaking about so-called non-patient stakeholders. That, of course, is a somewhat artificial distinction since all of us will be patients or are caregivers at some point.

I think PCORI has a great opportunity to engage those groups and I'm happy to do so. As Gene said earlier, we've not really talked much about engagement, at least from the staff perspective, and so, I would be delighted to take your comments and invite any sorts of comments and questions when I'm done.

Let me just quickly give you a presentation outline. This is familiar to you because Judy did this, as well. We did linear

presentations to be pretty organized. I'll quickly talk about how we are defining these stakeholders that I am responsible for, talk very briefly about some of our engagement activities, and, again, welcome your input, give you a timeline and then talk about potential areas where we may be able to measure our success.

So, this, again, picks up on our earlier discussion about the Concannon definition of, again, the non-patient stakeholders, individuals who are not patients, not caregivers. We tried to group them. The groups get larger and larger, but at this point, I think we're to eight, begin with clinicians, clinician associations, of course, the professional societies, also look at groups such as purchasers, researchers who I guess might be termed the usual suspects, and then educational institutions. We did not call out quality specifically because we realized that most of these entities, frankly not all of them, had some sort of component of quality in them. Also, wanted to stress that we are going to be seeking the input of

nontraditional stakeholders. That will be the tough part of our job as both Sharon and Ellen have said, but we do wish to reach that family physician in upstate New York.

I'm going to quickly recap why we'd like stakeholders involved. We'd like them to give us their questions, what are they interested in learning more about, and then later help us prioritize them. Secondly, we want them involved in all phases of the research, including the review process. Dissemination is also key. How do we get the word out to people about what PCORI has done? And then, lastly, as many individuals have said, we're a learning organization and we would like feedback and information on how we're doing. What works and what doesn't.

So, in terms of the first issue and asking the right research questions and prioritizing them, we plan to do that a number of different ways. AHRQ has done a lot of work on this in terms of reaching different stakeholders. You can certainly do it one-on-one, organizational meetings,

interactive websites. And so, we'll be looking at that sort of information. But we'll also look to our own Methodology Committee Report and any sort of future research on how best to do this.

One way, perhaps, may be to convene workshops on key topics. What are some of the topics you're interested in and how would you prioritize them? Our feeling really is you get a lot of different stakeholders around the table and then you can generate these topics and ultimately prioritize them.

In terms of reviewing proposals and conducting research, Martin talked about that earlier today, and, ultimately, the goal is to have a cadre of PCORI reviewers. These would be reviewers from different stakeholder groups, again the so-called non-patient stakeholders, who would look at these proposals for impact, for example.

Getting back to dissemination, this is absolutely key. We're going to work closely with AHRQ on this, of course, because of their charge in the statute, but we obviously want to look at

research and how best to get out the word and the information about PCORI research in an understandable language.

One example, and I know that Gail has questions about this later, is some sort of baseline clinician survey, and this would be the sort of thing like what do clinicians know about clinical effectiveness research? Do they use it? Do they trust it? So, that may be one idea for finding an answer to what improves dissemination?

Also want to take advantage of the already established networks out there. Every professional society I know has its own network and probably would be willing to work with us to get out our PCORI research or some other results and that's something we would like to do as quickly as possible. Our goal, of course, is to really get this information out into the hands of patients and clinicians fast.

The last reason I'll talk about briefly is some sort of feedback, how are we doing, what works? Are we having an impact? It really doesn't

make much sense to go to all these efforts and not really change the health care system or how researcher information is delivered. Again, PCORI's a learning organization, as we all say, and we want information from our stakeholders about how we are doing.

One of the things I started doing when I meet with different groups is say let me know if I'm doing something that's not helpful or something I could be doing better. How would you like to be reached? How would you like to be in touch with PCORI? And we'd ultimately like to take that information, change our models, and reach out to stakeholders in different ways that are really appropriate to them. You need to tailor a lot of these efforts very individually to the different stakeholder groups. One size really does not fit all.

So, now I have two busy slides for you. Do not have to go through all of them, except later at your leisure. I will just describe one of the points on this. Again, this is the clinician

survey that I was talking about as perhaps giving us baseline information about clinicians and how they view clinical comparative effectiveness. And, perhaps, this is something that we could even repeat so that we could do it longitudinally, have their views changed over time. That would potentially be an interesting question to answer.

On the next slide, again, just a number of activities from April until the next board meeting in September, but I did want to respond to Dr. Clancy's question about the Capitol Hill briefing. In fact, we do have a couple that have been set up and we'll be talking with them about the PCORI funding announcements as well as the MC Report, and I believe that's happening in 9 or 10 days. So, it's literally around the corner.

Let me quickly finish up by talking about, again, these potential areas for success using the classic structure process outcomes measure. You see a lot of process measures, we're a new organization, but, obviously, the goal is to get to products or information that the public can use. I

cite this clinician survey again as an example of an output, but would really like your ideas, and I know Anne will talk about that later. In terms of outcomes that we can really look at and present to the public and to patients and clinicians.

So, just to conclude, lots of different stakeholders, eight different buckets at this point. They really need to be reached in different ways, but I am very committed to reaching all of them and I'd be happy to take your questions. I believe now though I need to turn this over to Anne for some of the other questions for the Board on which we are seeking your advice.

CHAIRMAN WASHINGTON: Could I just before we go to Anne, because there may be questions in the same way we had for Judy.

MS. HILDEBRANDT: Sure.

CHAIRMAN WASHINGTON: Points of clarification and/or specific comments directed to you, Susan.

MS. HILDEBRANDT: Certainly.

CHAIRMAN WASHINGTON: And so, we're going

to start with Allen and then Bob Z. and Sharon, Steve, Carolyn, and Michael.

DR. DOUMA: When you talk about dissemination, do you also include uptake utilization?

MS. HILDEBRANDT: Absolutely, and that is my error if I did not include that on the slide because, of course, we want to get the information out, but we want people to use it.

DR. DOUMA: Yes, that'd be great. Yes, I think it's important to have some other word or multiple words always going forward.

MS. HILDEBRANDT: Simply to clarify, sure.

DR. DOUMA: Yes.

MS. HILDEBRANDT: That's a great idea.

CHAIRMAN WASHINGTON: Okay, Bob Z.?

DR. ZWOLAK: Bob Zwolak, Board Member.

I'd like to pursue just a second if you would what your expectations are from the clinicians and what your survey would be for clinicians because I've probably given 25 talks in the last 6 months about PCORI, and the physicians

who know us or have heard of us are the researchers. And the other 95 percent of doctors in the trenches with their shoulders to the plow, they're not likely to apply for research grants and they're not likely to pay much attention to PCORI until the results of the research that we fund finally hit the publications and the journals.

And so, what are you looking for when you run your survey of physicians? This is sort of a parallel question to what Gail asked a little bit earlier, but in a little different perspective.

MS. HILDEBRANDT: Yes, that's a great question because, again, we want to move away from the so-called usual suspects. The researchers that are already keenly interested in what we do and get this to the clinicians and to the different associations. We've just started thinking about this survey as the way that we can actually reach that answer. How should we involve, how can we determine how best to get clinicians interested in CER? If they had it, would they use it?

So, I almost would want to turn the

question back to you and others on the Board for ideas. We started thinking about it internally and looking at different ways that we could structure it, but your question is a good one because we don't want this survey only to go to the research physicians, we want it also to go to practicing clinicians.

DR. DOUMA: Can I follow-up on that?

CHAIRMAN WASHINGTON: Sure. Allen.

DR. DOUMA: I mean, it seems that anybody over the last couple of decades who is interested in CER would like to know what the practicing physicians think both in the research level, but also in the application level, and it seems like given that, there must have been a bunch of surveys done by people already of what the physicians think. Except that the question that wouldn't be asked is: What do you think of PCORI, which is probably not particularly relevant to this particular survey, or it may be. So, I want to make sure that we don't reinvent the wheel and that before we do a survey, we decide what questions

we're trying to get answered.

MS. HILDEBRANDT: Right.

DR. DOUMA: With the survey. Otherwise, you end up with a lot of information and no data or a lot of data and no information. That's what I meant.

MS. HILDEBRANDT: Right. Yes. Whenever I start a project, I really start with the goal and move backwards. And so, we are still trying to determine what information we specifically want and that will influence exactly how this is structured. And so, again, this is something we've thought about fairly recently, and so, we do seek your feedback.

CHAIRMAN WASHINGTON: I see other hands, but Leah has a comment on this point right here. Yes.

MS. HOLE-CURRY: Just to play off of Bob's comment I think is that it struck me that you mentioned the eight categories, but your survey is for a particular group and I think that's fine if we have particular questions of any one group, but

it may be that we're seeking information about, as Sharon said earlier, consumers of our research or it may be that we want to engage them in the research process, but it may be that you shouldn't focus necessarily on one group yet, but on the questions that we want to ask because I would have the same comment about state policymakers. I was just sharing with someone that even my role on PCORI is not well understood with my counterparts in state policymaking, even with some that are very involved in other evidence-based decision-making and research. And so, you may have the same issues across groups that we would want to consider asking the same type of questions depending on what it is.

MS. HILDEBRANDT: I agree. I think that's a terrific point.

CHAIRMAN WASHINGTON: So, we have Sharon, Steve, and Carolyn, and I see some of the others, but we have a comment on this particular issue from Sherine, please.

DR. GABRIEL: Just a quick comment on this issue, I agree with what's been said, that actually

reflecting on things that Steve has said repeatedly, you might want to think about not only or in addition to the clinicians with their shoulders to the cloud, the leaders of clinical systems because they're consumers of CER information and have somewhat different interests. They want to see how to improve the practice based on this information. So, I could imagine some meaningful questions directed to that group.

MS. HILDEBRANDT: Great.

CHAIRMAN WASHINGTON: Okay, Sharon, Steve, Carolyn.

DR. LEVINE: Yes, my comment was about the notion of a clinician survey, a physician survey I think is what you described in here, and I've had 20 years of experience trying to do physician surveys, and there are only 3 circumstances under which a physician will respond to a survey. It has to come from someone they know and trust and whose motivation they know and trust. They have to see in answering it a clear line between taking the time to do it and making their life easier. And

either they have to be paid for it or fed.

[Laughter.]

DR. LEVINE: Or fed while they do it.

UNIDENTIFIED SPEAKER: [Off microphone.]

DR. LEVINE: Yes.

UNIDENTIFIED SPEAKER: Shoulders to the cloud.

DR. LEVINE: Even when it's in their best interest to do so and when the results have a positive impact, you're lucky to get 40 -- 40 percent is fabulous. And so, I think I really agree with what Leah said, which is what information do we need from those who are most likely to use and benefit from this work and make it available and accessible to those who ought to be using it?

MS. HILDEBRANDT: Right.

DR. LEVINE: And so, the issue of trust and intermediaries, the issue of system leaders who actually do this. The truth is if you tried to ask a bunch of physicians what do you know about CER, you're going to get nothing back because it isn't

relevant to what I do every half hour from 9:00 to 6:00 every day, and so, I do think with the consumers of the research and the evidence that's generated, we need to think about where do they go for trusted information and how do we produce information that those trusted sources have a way of deploying and making available at the point of care to make physicians' lives or clinicians' lives simpler and patients' lives better? So, I would put the physician survey-I think you need to reformulate that idea in terms of, again, what it is you want to get out of this that will help with PCORI's work.

I think it's interesting, I know we've talked in the past about branding PCORI and producing product or products which I've had a hard time understanding how products are different than research results for a research institute. I'm not sure that branding PCORI ought to be what we're worrying about. I mean, I think what we ought to be worrying out is producing high-quality information that is of use and high utility to

patients and caregivers and to those who provide care to them. PCORI recognition will come as a result of that.

MS. HILDEBRANDT: Thank you.

CHAIRMAN WASHINGTON: I have Steve, Carolyn, and Michael.

VICE CHAIRMAN LIPSTEIN: I wish I had said this during the public comments, instead of board member comment, because I'm going to use a personal anecdote to kind of make my point, I think. Many of you know I live with somebody who has MS, and so, because of that, we are big contributors to fundraisers for and supporters of the National MS Society. But one of the things we've learned as a result of that is that most people we work with in that regard don't have MS. So, you've got the patient advocacy group that give you a different perspective on the disease and then what I've come to learn is that somebody who has MS with economic means, such as my wife and me, as a family person, we're one segment, but then people who live with MS who don't have means are a completely different

cohort.

And then the difference between somebody who is mobile with MS versus someone who's immobile with MS is very different.

So, as you engage patients or as you engage people who take of those patients, if you go to the MS centers across the country to engage, that would be in Susan's world and I think if you go to engage the patients in those MS centers, that would be in your world. And so, I guess I would encourage you to make sure, A, your worlds overlap and, B, that you don't consider patients with one condition as one group of patients, that the cohorts not only need to be micro segmented, but it's really important if you're going to do patient-centered outcomes research.

I could give you similar examples, I think and Ellen could, too, in the cancer world. I can't tell you how many people gave my brother advice that had stomach cancer and they had prostate cancer. And so, when we get at what are the issues that really apply to me, it's almost -- I hate to

use this word because it's an economic term, it's a micro costing, but you also need to do micro segmenting of your stakeholder strategy in order to get to the important differences among patients.

CHAIRMAN WASHINGTON: Okay. Carolyn, and then Michael and Christine.

DR. CLANCY: So, just quickly, I'd like to associate myself with everything that Sharon said. I did note when you said "relevant to what I do every half hour." Am I to interpret from that that Kaiser clinicians get a half an hour per patient encounter?

[Laughter.]

DR. CLANCY: This could be quite a recruiting tool.

DR. LEVINE: Why do you think I said it?

DR. CLANCY: But it does bring me back to the point I wondered about, which is time. I think if you ask most docs what would make my life easier, it would be time. Some would actually mention other resources, but I think time is what many people feel terribly frustrated about and I'm

not real clear what we want to know. Do we want to know what we ought to be funding, what sorts of answers and problems they find challenging? Do we want to engage them in dissemination? Is it kind of sort of all of it and how do we make this really, really fast and easy?

So, these are not simple questions, it's not like oh, wait a minute, I got another PowerPoint slide in reserve. I understand that. But I'm sure that all the professional societies you know of that have their own networks are all competing for this mine space because I think a lot of practicing docs feel pretty overwhelmed right now and I don't blame them.

And what I think we've got to realize is that as we pump out more information, we may be asking them to commit more time to working with patients to process this because although we envision that these two sort of strategies are sort of separate, an awful lot of patients and probably the vast majority want to know what does my doc think? So, that's going to be pretty tricky.

So, I think we've got to be really concrete about what do we want from people. Do we expect that people are engaging all parts of that wheel and how do they do this with day jobs?

MS. HILDEBRANDT: Thank you.

CHAIRMAN WASHINGTON: Okay, Michael and Christine [off microphone] and then Larry.

DR. LAUER: Mike Lauer representing NIH.

As Carolyn pointed out, the challenges here are extremely daunting, but I think one of the major challenges in engaging physicians is not so much engaging physicians to use comparative effectiveness research, but to actually be part of it, to actually join the game, to come to the game as opposed to reading about it in the newspaper the next day. And, unfortunately, in this country, less than 10 percent of physicians are in any way engaged in the clinical research enterprise, and that could mean as little as enrolling 1 patient.

And furthermore, while about two-thirds of American patients would be willing to participate in clinical research, only 6 percent report ever

having been asked by their doctor to participate in a clinical research study. So, the way our system is currently structured, we have both an enormous potential, enormous reservoir for our physician and patient engagement in research because most of the patients and physicians are not part of it.

But that would be a very exciting area to focus on and if somehow you could get the level of physician participation in research, a how small it might be from six percent to 10 percent, you would have accomplished a lot. There are parts of the world and there are hospitals around the world where 80 to 90 percent of physicians and patients participate in clinical research. We had histories of specialties like pediatric oncology, where participation in clinical research was the norm, it was the culture, and that's engagement, and you can imagine like in the case of pediatric oncology when there was a time when nearly all doctors and nearly all patients participated in research, research results got implemented because they were part of the game, they were actually there.

MS. HILDEBRANDT: Great point.

CHAIRMAN WASHINGTON: Christine and then Larry.

DR. GOERTZ: I mean, it's exciting to be at this point and I'm really looking forward to seeing all of you move forward with this process.

Just a reminder, I think it's really important not to narrow our thoughts about clinicians to physicians. I think we have a tendency, you said clinicians, but then you talked about a physician survey and then a clinician survey, and I think right now when we talk about health care providers, we tend to be focusing more on physicians and there are just so many other health care provider groups that I think are very, very interested in comparative effectiveness research and what we're doing with PCORI and I just want to make sure that we're not in any way leaving them out.

CHAIRMAN WASHINGTON: Okay. Very important point.

Larry and then Harlan.

MR. BECKER: I wanted to reflect on Rochester, New York, 20 years of doing employer roundtables, patient roundtables, physician roundtables, the African-American and Latino Coalition Roundtables. And I looked at your five questions and I thought well, what's different, and we're focused on those things, but something unique happens in Rochester, and that is every Thursday for at least two hours, all of the stakeholders get together, patients, clinicians, employers, pharmacy, we've got them all. And there's a table of 20 people and we've done a whole series of initiatives over the past five, six, seven years with this group.

And I think that one thing that happens at that group is we begin to share our perspectives, our barriers, and our enablers, we begin to understand each other, but the solution that we build is richer because we listened to each other's perspectives. And so, as you're thinking about doing roundtables, as opposed to always doing focus roundtables with this slice of patients or this

slice of clinicians, it may be very instructive to put them all together in the same room and work on those same problems.

CHAIRMAN WASHINGTON: Okay. I think you're going to hear that as a recurring theme. I've heard it at least three times in the discussion.

I have Harlan and then Allen.

DR. WEISMAN: I was not going to say anything like what Larry just said, but I totally agree with what he said and I think the model for what you're talking about is this board. I mean, we're all strange bedfellows at the beginning, and I looked at --

UNDENTIFIED SPEAKER: [Off microphone.]

DR. WEISMAN: Well, yes, I think Rick and Freda and I talked a lot in the first month or so about the way some of you looked at us a little strange.

[Laughter.]

DR. WEISMAN: So, anyway, but what you find out after a while after you build

relationships, you find out people are more on the same page than not and you let go of the barriers, and I absolutely agree with what Larry said.

I do think this time issue though is a big issue that Carolyn was talking about and that, to me, is a subject of research which I hope somebody presents to us. I was talking to my own internist about PCORI and he asked me about it and he said are you still doing that thing?

[Laughter.]

DR. WEISMAN: I mean, a lot of the doctors who do know about PCORI are thinking about us as another burden that will be placed on them and telling them what to do and all of the constraints of the health care system that have gotten their way of doing what they want to do to practice good medicine, good health care. They can't because of all the bureaucracy, and we talked more about that, but he's a concierge doctor and you can think of that as an elitist thing and actually it started out that way, but he spends an hour with me every time I see him once a year and he really delivers

very good health and lots of things that surround the way he deals with patients.

But the group that he belongs to is now demonstrating that they're improving outcomes and they are on a pilot basis. It's a national group as far as I know, are taking on Medicaid patients and showing that if you actually talk to people, give caring as well as care, all of a sudden, people start feeling better and you start having the open, nice relationships that people want to have, that allow people to maintain health and get themselves better, and I'm hoping that somebody in one round or another puts that kind of research proposal around us and shows that touching and talking actually is a way of healing and healing is a good thing.

CHAIRMAN WASHINGTON: Allen, you have the last word before we ask Anne to really wrap this up.

DR. DOUMA: Well, thank you very much. A couple of comments. One is if you go back to the list of Concannon's categorization, but there's one

category that's not there and that is the group of folks that are focused primarily on prevention like public health employers, schools, which leads me to the whole self-care arena and I appreciate, Judy, when you commented about patients, we're all patients, therefore. I think we need to get comfortable using terms that don't include patients necessarily, and Christine reminded me that we have to say things over and over again.

I've said this a lot, but I want to come back, is understand is almost every medical or health decision is made by somebody outside of a clinical setting, and so, important stuff. We need to focus on it and be able to talk about consumers even and people and patients are sort of a subset of the rest.

CHAIRMAN WASHINGTON: Okay. Well, again, thanks to all the Board members for your valuable, at least I think it's valuable, your valuable comments and input.

It's clear that we have a great deal of work to do in this arena, but as Leah said earlier,

all of what we're doing now is foundational and this is a case where we're just trying to establish the foundation from which we would build on and we all recognize that this is early on, but what you've heard, I think, is enthusiasm from the Board for participating in establishing that foundation, and, in fact, encouraging all of you to not think of this as a responsibility of Joe and Anne and Judy and Susan, but really to use the support and decision-making systems that are in place, particularly the COEC, as well as Dissemination and Communication Workgroup. So, it should be that when something comes here it's benefitted at a minimum from the input and/or guidance and/or criticism, constructive, but also rigorous, of those groups that we already have in place. And so, we would want to see that that is considered the norm as we think about presentations related to this critically important area.

And with that, Anne.

DR. BEAL: So, thank you. These have been actually outstanding comments and one of the things

is we were thinking about this presentation. I actually posed the question to Judy and Susan and really pose the question of what are our measures of success or if we were going to go through this exercise on an annual basis and have the Board hear about our activities around the engagement, what is it that we would say a year from now that is different from what we're saying now? And not just we did this, we had X number of workshops, we met with X number of organizations, but the question that we're really struggling with in thinking about at the staff level and are, in fact, asking the Board for guidance on is how do you measure success? How do we know that we're having the desired impact?

And so, I think, Sharon, your comments about the physician survey are extremely well taken because they are there. We are an extremely difficult group to get results from, but I will say that as we start to think about it, we went back to the vision statement and we went back to the mission statement, which talks about use and trust

of PCOR and talks about use of information that we will be producing. So, how we're going to know that we're having that desired effect that we said we want to have from our mission statement.

And so, I think that that is a longer conversation, and, in fact, we've had this preliminary conversation with COEC and it is not an easy discussion. But what I will say is just having done programs before, I think that as an organization, what we need to see is not only sort of the North Star and the aspirational goals, but what are you going to hold this accountable for? So, a year from now, when this engagement staff are making the same presentation, what is it that we will be held accountable for? It's not a just process measure, but really ties into the mission and the vision that you all have created.

And so, I think that this should be an ongoing discussion, but I think that it's a critical one because it helps guide us from an execution perspective, having that vision that you all set. And so, whether it's a survey or not or

if it's a survey of nurses or PAs or whatever, that's actually not the relevant question. The relevant question is: How do we know we're having that desired impact and how can we have that sort of vision to execute?

CHAIRMAN WASHINGTON: Harlan is going to give us concluding comments after Anne.

[Laughter.]

DR. WEISMAN: Well, I will then, and I think you opened it up, Gene and Leah, with some comments when we began this kind of discussion, and a lot of the discussion which was very good and the presentations were very good and just intuitively, it seems like the right thing to do. A lot of it is framed in what we want to do and then how we want to do it.

The why we're doing it is missing and the why we're doing it is called strategy and, Gene, you talked about how does this fit into all the other related things, whether it's Methodology Committee, whether it's the research, and I have to tell you I think I could take some educated guesses

at it, but I'm not really clear. It's wonderful activities, but, as you said, the true measurement cannot be we did a lot of activities.

It's hard to judge whether what you were doing is the right thing and how you're doing it is the right way if I don't know why you're doing it, and I think we need that kind of framing, and that, to me, then becomes the measurement. Because the why you're doing it has some kind of outcome that we desire, a result that we desire, and did we achieve that result? And that's independent of the number of surveys, the number of advisory committees, and that was one of my questions. Advisory committees were on these slides, Methodology Committee's doing advisory committees.

I'm worried that we're going to have advisory committees running into each other tackling the same things and that once you decide why you're doing something, then you can get into what are the best strategies or tactics to doing it that will give us that clarity. And I'm not laying this on you. I think that's a challenge to all of

us who are involved with the institute.

CHAIRMAN WASHINGTON: Thank you and thanks to our colleagues Anne and Judy and Susan and all of the others who work with them on bringing us to this, I think, auspicious point, recognizing that going forward, we've got work to do, but the great news is we have enormous talent across our PCORI enterprise in the form of staff, but also board and eventually in the form of these advisory groups that we are going to organize and coordinate. So, thank you very much.

I've got to give you a break for ten seconds just to regroup, and then Steve. Well, I'm looking at Harlan. So, we're going to have a stretch break here for one full minute and then Kerry is going to introduce the next session.

[Recess.]

CHAIRMAN WASHINGTON: [Off microphone.] I think this is the last welcome I'm going to issue today. Welcome back to the Board of Governor's Patient-Centered Outcomes Research Institute. I want to make sure to credit or blame the individual

responsible for all of these breaks. I received two articles from Harlan W. regarding best practices around breaks at Board of Governors' meetings I'm trying to ward off the third one, Harlan.

[Laughter.]

CHAIRMAN WASHINGTON: I'm going in the right direction.

DR. DOUMA: Are these CER-based studies?

[Laughter.]

CHAIRMAN WASHINGTON: A very good question. I need to go back and take a look at them.

DR. WEISMAN: As long as you take a look them [off microphone].

[Laughter.]

DR. DOUMA: And I'm going to send it to everybody else.

[Laughter.]

CHAIRMAN WASHINGTON: Thank you, Allen. Thank you, Allen.

Okay, Kerry, please.

MR. BARNETT: Kerry Barnett on the Board.

Just a quick introduction, Mr. Chairman, I don't know if we're going from the sublime to the mundane or the other way around, I'm just not sure, but at the last meeting, we did talk about the process behind our audit and that at this meeting, we would report back on the outcome of the audit, and that's what we're here to do. But before we do that, and Pam Goodnow is going to be the primary presenter here, but before we launch, this is Pam's first board meeting, and we just want to make sure everybody had a chance to meet Pam. Her role is to lead the sort of finance and accounting function of PCORI and she's very much hit the ground running. She's doing a great job adding value, putting the right systems and controls in place and even if you haven't met Pam yet, I promise you that she is helping you sleep better at night.

[Laughter.]

MR. BARNETT: So, we really appreciate having you onboard.

Just a quick reminder, under our statute,

we are obligated to conduct an annual audit and there's a little bit of misunderstanding around this. Under the statute, we go out and we hire and independent audit firm to conduct that audit and then the comptroller general will review that audit and then report on it to Congress. There's a little bit of confusion. Have people have assumed that it's the GAO who actually comes in and conducts the audit and that's actually not the case. It is true that after five years of operation, there's another type of review that the GAO will come in and do and it's kind of an effectiveness audit that'll look at all of our programs, all of our activities and issue a much more comprehensive report to Congress about what we've been doing.

But we've now completed the first audit cycle. We've engaged an outside auditor, McGladrey, and you'll hear more about this in a minute, and we've gone through the audit process. The process came out very well, due to a very great extent to once again Pam. There was no suggestion

of problems with our controls, the accounting of funds, anything of that sort.

So, it's really very positive. Although, I do want to note that because this was our first time through this process, there were a number of issues that we're sort of facing for the very first time, and, frankly, the GAO was facing for the very first time, as well, and it's, once again, a reminder of what an unusual entity we are that some of these issues are being confronted for the first time. It raised some sort of fundamental definitional issues, for example, with respect to control over the trust fund and that sort of thing.

So, there haven't been any easy answers and sometimes getting the answers has frankly taken longer than we might have expected, but, for example, with respect to the control of the trust fund, one of the primary issues that would surface was that because the trust fund is earmarked for us and only for us, that, in fact, unlike the way we had previously been accounting for the trust fund, the GAO found that it is important that we include

the trust funds on our balance sheet, even if we haven't drawn down those funds yet. And so, that's a very important adjustment that we had to make through this audit process.

So, that's the only real significant substantive issue that arose, but it's important, I think, for that the Board kind of under the circumstances understands the flow of the audit and the various issues that were raised throughout. And so, with that, I'll turn it over to pam.

MS. GOODNOW: Great, thank you. Can everyone hear me? Good.

I'll start out by saying, as Kerry did, that McGladrey did complete what was our first audit and they did issue an unqualified opinion and that audit tells you that our books were substantially in compliance with generally-accepted accounting principles, and that's the normal audit that all of you are used to seeing in your daily businesses.

There were two periods involved. It was our first audit, but we had the November 10th,

which was inception through December of 2010, and then the full year of 2011 that were in this audit period. There wasn't a lot of activity in the 2010 year, but there certainly was in the 2011 year, although nothing compared to what we're going to see moving forward. So, from that perspective from an accounting perspective in terms of what we've got to say here today, there are not a lot of surprises and there are not a lot of big numbers in terms of what we spent and what we've taken in.

Because of the money that we do receive is from direct appropriation by the government, that makes us subject to the yellow book, and those of you that are in the government know these standards very well, but they're essentially a set of standards that are governed, the accounting that takes place and the audit procedures that take place for people that manage government money, whether you're a non-profit or a government organization or someone like us who sort of has a unique, very small little niche in the non-profit group, but doesn't have a good body of legislation

or regulation that tells us how to conduct our business and that was one of the problems that Kerry alluded to in terms of being able to know how to handle various things from an accounting perspective.

There is a report and it might have the longest name of any accounting report in the entire world, but Independent Auditors Report on Internal Control over Financial Reporting Compliance and Other Matters, and it's based on an audit of financial statements in accordance with government auditing standards. That report is page 17 and 18 of our official document and what the yellow book is looking at is to give assurance on two things: that we are in compliance with government accounting standards and that we have internal control over financial reporting is the first thing that they look at and the second is compliance and other matters, whether we've abated any rules and regulations out there that we are supposed to.

Over financial reporting, they did a finding and it is, as Kerry was speaking about, the

recognition of the appropriation and the timing of when we recognized it and the fact that we should have included the entire PCORI trust fund on our books and records. We didn't discover it until the GAO said the government isn't reporting it and we had just assumed since the Treasury had control of the monies and we had to ask for them that there was certainly no real sense of control over the fund itself.

The fact of the matter is from a technical accounting standpoint, the terminology or the point that they looked to was that there is no right of refund in the legislation itself. So, once that money goes into the fund, it is there, it can't be taken out by anybody else, and as a result, they decided that we should report it on our financial statements.

What that does and the financial statements that you have been used to looking at here in this group, you recognized the first $10 million in the first year 2010 and then the $50 million appropriation less the 10 that went to HHS

and the AHRQ in 2011. What is true and there's a little nuance here because we established a calendar year as opposed to the government fiscal year.

So, we have what in essence was three government appropriations that came out in the period of our two fiscal calendar years, but three government year appropriations that came out. And so, when they told us to look at the entire PCORI trust fund, we then had to go back and change the accounting methodology that we were using not only for recognizing revenue, but also interest because we did not realize that the Treasury was investing all of this money. The assumption was that it wasn't ours to spend. The good news is it is, and so, it is now reflected in our financial statements and it is that other source of income that we have. We can only have one source, but because it's generated from the actual appropriation money then we're entitled to those funds.

So, as I said, basically, it's these two issues that culminated and the first issue putting

the PCORI trust fund into our books and records would not have been a finding had it not been that it crossed the fiscal years and the reason for that was that when we initially put it onto our books and records in working with McGladrey before the audit went to GAO, we took it in as differed revenue and recognized the money on the balance sheet as being monies held by the fund for us as an asset. The problem with then realizing that the fiscal year played a part in this led to the fact that we had to recognize that revenue and then our financial statements had been materially misstated because instead of revenue for the 2 years of 60, we had revenue of another $120 million that is in our -- now and we go through the report here today, you'll see that in our income statement.

So, we took it into revenue and that is the reason for the finding and all of that, the financial statements that are produced and that are on file and now available for the public, all of those corrections have been made. Moving forward, we'll treat those monies as ours. We've been given

access to the Treasury Department online banking system so that we can go in and on a regular monthly basis, you'll now see your financial statements in that format because we won't have to wait for the end of the year for them to tell us.

DR. CLANCY: May I?

MS. GOODNOW: Yes.

DR. CLANCY: So, just a quick question of clarification. Carolyn Clancy, Board Member, Director of AHRQ.

This fourth point in the blue here, technically, and I'm thinking of the language of the statute now, I think it should say total funding of the PCORI allocation of the PCOR Trust Fund.

MS. GOODNOW: Okay.

DR. CLANCY: Because 20 percent of the PCOR Trust Fund is allocated directly to HHS, AHRQ, and does not come through PCORI.

MS. GOODNOW: True, although and you'll see when we get to the slide on our revenue and our expense that what happened initially, the first

funds were put in in 2010 and they weren't distributed to you, to AHRQ and HHS for some period of time. What happened was that the revenue that was the interest income that was generated then went to you and not to us. And --

UNIDENTIFIED SPEAKER: You did well.

UNIDENTIFIED SPEAKER: Well.

[Laughter.]

MS. GOODNOW: Yes.

MR. BARNETT: She can go into a ton of detail about all of this and for the sake of time, it's probably not necessary, but the bottom line is that money hits the trust fund, and it moves out to you --

DR. CLANCY: Right.

MR. BARNETT: And still, whatever is in the trust fund at the time that an account is made, it is what should be reflected on our balance sheet.

DR. CLANCY: That's fine. I really just brought this up because, not to be overly picky, but based on a recent conversation with some folks

at OMB.

MS. GOODNOW: Sure. Okay.

DR. CLANCY: Is that they were taking issue with me about how PCORI referred to the trust fund.

MS. GOODNOW: Okay.

DR. CLANCY: So, I was just reflecting that back.

MS. GOODNOW: Noted.

DR. DOUMA: Pam, with regard to when the money hits the fund, with general fund money the first three years at least, I know it shows up October 1, right?

MS. GOODNOW: It's supposed to.

DR. DOUMA: Supposed.

MS. GOODNOW: It doesn't necessarily arrive on October 1st, but it is we have a lot of money to do at that point.

DR. DOUMA: Okay. As we get into our revenue or funds coming from fees, will the assumption be made at the beginning of the fiscal year? Will a calculation be made at what those

fees are going to be in subsequent year and all that money will show up at the beginning of the year or will it dribble in over the quarters?

MS. GOODNOW: Well, as many of you know, the IRS has released their proposal and we're in the comment period now for how those taxes are going to be allocated, but they are suggesting that they're going to collect them through benefit programs and excise tax returns. So, that is a completely different revenue recognition methodology. It may come in for some significant period of time after October 1st because depending on when your insurance plan year ends, you've got some time to file that report and then for them to tally up and see what the tax is and those are some things that we are looking at in the Finance and Audit Committee here moving forward because it's going to play a big role in our cash flow and when we can expect the monies to hit.

DR. WEISMAN: Can you clarify this, now that we've gotten all this clarified and how we recognize it, but the U.S. Treasury is the official

trustee of the trust fund?

MS. GOODNOW: Yes.

DR. WEISMAN: So, even though the money has been allocated to us and we still go back to Treasury and ask permission of the trustee? How does this work?

MS. GOODNOW: We don't actually ask permission, which is what we discovered in terms of the fine terminology and talking to GAO. They mechanically distribute the money to us and they hold it until we need it, but we simply tell them what we need, when we need it, and then they transfer the money over as if you called your banker. The one determining that we needed is us.

CHAIRMAN WASHINGTON: Okay, we have Bob or Robert Z.

DR. ZWOLAK: Bob Zwolak, Board Director, Board Member.

Pamela, first, I want to recognize your incredible work because having watched this over the months, you kept getting different answers from different places and finally rooting your way down

to what we think is the real truth. So, congratulations.

But the question I had relates to our fiscal year. We, I believe, made a decision about what our fiscal year would be based on information we had at the time and we chose a calendar year. Is there a benefit to having the calendar year as a fiscal year or would it be more beneficial to PCORI if we were to coincide with government's fiscal year?

MS. GOODNOW: That's a discussion that Kerry wants to have moving forward, but I think one thing to realize is that if we were getting revenue on a regular monthly basis or quarterly or whatever and once we find out how this tax is going to actually be allocated into us, we may want to consider a government fiscal year. Right now, we've got only one money that comes once a year, so, all of your benefit plans, your [inaudible], your pension, all of that stuff has to be reported on a calendar year. So, I can see where a calendar year made the most sense. We had one entry before.

Once we find out how they're going to manage the tax, I think we do have to seriously sit down and consider what kind of complications we're going to have. We can't spend money before we get it and if there is a big delay in getting that tax money, we're going to have to know that this project three years out is spending 2011 or 2013 or 2014 or 2015 money and that's going to be very hard to keep track of if we have a different fiscal year than the government fiscal year.

VICE CHAIRMAN LIPSTEIN: Bob, the only thing I would add to that is when we made this decision, at that time, we weren't using just accounting criteria.

MS. GOODNOW: Sure.

VICE CHAIRMAN LIPSTEIN: In that time, it was very important to board members that at every opportunity we get, we remind ourselves, as well as the public, that we're a private, independent organization, and, actually, this reminds Treasury and GAO every time they have to reconcile that we're not a government agency and not to be treated

as such. So, it is a good reminder. So, I would just encourage us when we make those determinations, Pam, that go beyond just accounting considerations.

MS. GOODNOW: Oh, sure, and there are others. I mean, any monies to the Board, all of those kinds of things come out in audit, and so, it's much easier to keep track of on a fiscal calendar year where we've got a 1099 or a W2 to talk about someone's income rather than trying to do it on a government fiscal year. So, there are many, many considerations that we should take into account.

MR. BARNETT: Pam, I know you've got about two or three more slides here [off microphone].

MS. GOODNOW: Sure, and, in fact, I think I've spoken to a lot of this. What I will do is just to take you again to the accounting for the trust fund and this will only just show you what we ended up with ultimately, where in 2010, you see that the government fiscal year 2010 appropriations and 2011 coming in, less the money to AHRQ and HHS

with the interest that they had accrued, and that left us $49 million going into 2011.

The allocation of the 150 from the government fiscal year 2012, which we received in November less the money to AHRQ and HHS plus our interest earnings left us with 158 going into 2012, and part of the model that we're building for how we allocate our money is very much dependent on accumulating these monies in the beginning years so that we have some cash already accumulated in the bank in order to pay for the funding to go out for the contracts that we're awarding.

This is the balance sheet. Again, it just shows you that you've got net assets of $160 million going into 2012. The amount of the actual PCORI trust fund, you could go up and match that to the Treasury fund at any given point in time, and as we draw down money, it shows up in cash, so, if there has been a draw for expenses we're expecting in a month or the upcoming expenses, you'll see it under the cash line, all the other money and cash is held by the trust fund.

The revenue statement is, again, because we've got so little activity other than our revenue, which is the big driver, you'll see that $50 million in revenue for 2010, $120 million for 2011, plus our interest income and then the program expenses that were virtually nonexistent in 2010, in 2011, obviously building out our infrastructure and doing all the work that we've been talking about today accounts for all of the program costs here, and then general and administrative costs of actually getting an office and getting it operational. And the entire auditor's report is posted and if anyone has any questions after you've read any of the notes, please be sure to give me a call.

CHAIRMAN WASHINGTON: Okay, I would underscore for everyone on the Board as well as those listening via the webcast that all of this information will be available immediately on the website. So, for board members, if there are questions that you feel like we could hold that you could get to Joe and/or Pam, I would ask you to do

so, but I'm reassuring the public that this will be available in the next day.

And so, with that in mind, Rick?

DR. KUNTZ: First of all, congratulations. This is great to be able to get this all tied up and welcome aboard. We need you.

[Laughter.]

DR. KUNTZ: Is there a reason to have a statement of cash flows in addition to these other schedules to understand --

MS. GOODNOW: There is in the full report.

DR. KUNTZ: Okay.

MS. GOODNOW: We didn't really put it in because, again, our big number is just our cash from the appropriation. When we actually have some expenses that are program and overhead and built out in infrastructure, cash flow will be a little more interesting. It's a little boring right now, but it is in the entire document.

DR. KUNTZ: Okay.

CHAIRMAN WASHINGTON: Okay, Kerry?

MR. BARNETT: I'll just conclude by again

thanking Pam for her great work on this and just like so much of what we all do in life, going through things for the very first time is the hardest and we learn an awful lot and I think that's true of both us and the GAO in this case and we're confident that everybody has a better understanding of what to expect next time around and I'm sure it'll be much quicker and easier.

But that's all we have on this and if there are no other comments or questions, we can probably move on to the next piece.

CHAIRMAN WASHINGTON: I also wanted to give my thanks to Pam and welcome aboard.

MS. GOODNOW: Thank you.

CHAIRMAN WASHINGTON: Would you introduce, Kerry, one-liner?

MR. BARNETT: Just I'm going to turn it over to Larry, who has been very capably chairing the Standing Committee on Conflicts of the Interest that's been established. They've made a tremendous amount of progress, and, as you know, they have a very specific proposal on the table for our

consideration today.

And with that, Larry, it's all yours.

MR. BECKER: So, thank you very much. You have three documents that we laid after lunch in front of you, revised slides that will be up here. We have developed with Gail's help a table of the eligibility that I'll get towards the end and a bio NCV that I'll explain in a couple of slides.

So, I wanted to first of all thank everybody for your being open and frank. I think have talked to every board member but one and I have talked to people who aren't here today, Harlan Krumholz and Freda. I've talked to Francis. The only board member I was not able to get to is Bob Jesse, who's not here today. But, otherwise, I think I have talked one-on-one with everybody. And we've had a great amount of discussion and deliberation and, clearly, there are differing views that bring about and have perspectives that are very important to this whole issue of conflict of interest and it creates, I think, an appropriate balance for us.

So, we started this process, if you might remember, by putting together an ad hoc committee that recommended that we put together a standing committee on conflicts of interest and we pulled that together, and so, Bob Zwolak, Sherine, and I from this group and also Bernie Lo, University of California, also now the president, I believe it's called the Greenwall Foundation, Annette Bar-Cohen from the National Breast Cancer Coalition, Art Levin from Med Consumers.

Mark Feldstein, University of Maryland, he attended our first meeting and the reason you have another CV in front of you is that after that meeting, Mark felt that he had other time commitments and priorities and he needed to step down. And so, I'm going to put in front of you a replacement who also is in the journalism and media place.

Karl Seitz, the Council for the Committee from Harris Beach also much involved with all of the work that we did to put this together from the staff. Laurie Frank, Gail Shearer, and Melissa

Stern, who you all know and without them, I don't think we could do this and it was late on Saturday when Gail came up with the idea of putting this eligibility table together and I think that hopefully will bring clarity to exactly what we are going to recommend be done.

So, having said that, I think the first thing I would like to do is to propose for membership on the Standing Committee Professor Weisberg. He is a professor at GW. He has written extensively on health care communications and health care communications not only here, but in other countries. Argentina is where he's actually originally from and he talked about in terms of health literacy and in terms of how to communicate with individuals in the health arena. So, I've given you those things. By the way, it was yesterday literally I talked to him on Friday after we had done some work. I literally talked to him on Friday and he yesterday sent me the e-mail saying he actually would like to be considered. So, I apologize for not getting this all to you

like a week ago, but I didn't have the okay in the material until then.

CHAIRMAN WASHINGTON: Right. Larry, before you proceed --

MR. BECKER: Yes.

CHAIRMAN WASHINGTON: There's a process question. Kerry, I don't know the answer, but this would be a standing committee, right?

MR. BECKER: Yes.

CHAIRMAN WASHINGTON: In which case there's an argument for this going before nominations. This is someone who's being nominated for a standing committee. Again, I'm just raising the question at this point.

MR. BECKER: Okay.

UNIDENTIFIED SPEAKER: [Off microphone.]

CHAIRMAN WASHINGTON: No.

MR. BECKER: No.

CHAIRMAN WASHINGTON: No, no, we have a nominating committee for the Board.

MR. BECKER: You're right. You're right.

CHAIRMAN WASHINGTON: And so, anybody --

we've just had a meeting.

MR. BECKER: That's a fair point.

CHAIRMAN WASHINGTON: That's been appointed to a committee and/or for leadership, it goes to that group. And, so --

MR. BARNETT: Actually, the nominating committee does nominate the chairs of the standing committees, but the membership of the committees is actually your point.

CHAIRMAN WASHINGTON: Okay. Okay. So, in which case, Larry, I don't --

UNIDENTIFIED SPEAKER: [Off microphone.]

CHAIRMAN WASHINGTON: Right, that's great, but I don't think we should entertain this today.

MR. BECKER: Okay, that's fair.

CHAIRMAN WASHINGTON: So, I would say to board members just put this in your package, know that this is a candidate that we're going to be considering.

MR. BECKER: That's fair. Okay.

CHAIRMAN WASHINGTON: So, I'm sorry, Larry. Like you say --

MR. BECKER: Sure.

CHAIRMAN WASHINGTON: I didn't have time to think about it before now.

MR. BECKER: Got it. Absolutely.

UNIDENTIFIED SPEAKER: [Off microphone.]

MR. BECKER: Yes, right, if that's the most controversial thing, we'll be good.

So, the committee met in April and after an evening, a dinner, and then a full day of deliberations, we put together some recommendations, hearing from all of the various folks on the committee and all the perspectives that each of those folks brought forward. We put together a recommendation and we agreed that the mission of PCORI transcends any individual or groups, that the integrity and trust of the resulting research is the most important thing. Competing for grants in health and health care is very competitive. Researchers who can compete and produce meaningful results is a pool of scientific talent, expertise. Easily admitted, it's not an unlimited pool and we don't want to unnecessarily

exclude researchers who have scientific expertise to make significant contributions to us and to what we're trying to do.

We also talked about real and perceived potential for inside knowledge in allowing whether it's Methodology Committee members, close relatives, as the act defines it, of the Board or the MC, contractors, et cetera, to compete for PCORI funding, and, therefore, potentially giving those people an unfair advantage. We also agreed before the meeting that the Board members would not compete, and in the process of doing this, the ad hoc committee that served before, the chair and the vice chair of the Methodology Committee said that they would also be excluded.

We also talked about the rigid eligibility exclusions for the Methodology Committee and close relatives holds the potential to exclude some of the country's foremost scientists from competing for grants. And the risks stem from perception of advantage by obtaining some information in advance of others and then there were also the issues of

real conflicts involving the financial benefits.

So, with the help of council, we looked at the statute. The statute talks about real conflicts, it talks about a process for accusal and it talks about a process of disclosure. And where it talks about real conflicts, it talks about various aspects of it.

Since that's too small to read, the statute tells us and recognizes there will be conflicts and it provides a mechanism for recusal and it has some definitions around financial benefit and it lays out $10,000 is sort of that threshold and legal counsel said to us where there are standards, we should use those. Where they exist and are applicable, we shouldn't be creating our own because that would raise even more questions. But the statute is silent about receiving money from PCORI. It talks about getting money from other third parties, but it doesn't talk about money from PCORI.

So, in the course of our deliberations, Bernie Lo had said information's a market and he

made I think some eloquent statements around public knowledge and time and the ability for it to mitigate any advantage and Karl Sleight, who's the attorney, he came back and he talked about what Louis Brandeis and I said almost 100 years ago and that's sunlight is said to be one of the best disinfectants, and I think those statements were very persuasive on the committee.

So, the key question to consider is: Is advanced knowledge an advantage? Can it be mitigated? Can we figure out a process to do that? And by clarifying and documenting the activities of individuals and how they're involved, whether they're developing, articulating, or scoring the Public Funding Announcements, how are they involved and if we know that, putting through a set of filters so that we do that well, we create the right kind of firewalls. And so, we've agreed that going forward, we're going to create those kinds of processes to make sure that we understand who's been working on what and how.

And, hopefully, we'll be able to in

advance tell people as they come on to PCORI and to do some work for us, for example, as a contract, what the implication of that is.

As Harlan has said, the patient's "True North" and one of our panel members said that it was really important that we align what we do to the best interest of the patients, and that was clearly very important to her and that we protect patients' interest, that we communicate a strong conflict of interest policy, and then as we put the policy together, we thought about this ought to go out to public comment so that it is transparent and people understand about the policy that we're going to undertake.

So, the proposal. And with all that as background. First, the committee proposes that we communicate a strong conflict of interest policy and we put it out there and that every opportunity, information should be made public as soon as possible and we defined "public" means posting or linking information at our website. So, if it's out there, that sort of begins the clock of it

being out there in public. That we develop a series of filters to determine if there's potential for conflict of interest and the specific four examples that we used were developing the PFA, setting policies and requirements for funding, development methods of standards that are required by the PFA, and then the criteria for application scoring.

We also wanted to draw a distinction between input and involvement. So, input, the analogy I would use for input is the Supreme Court. When there's a Supreme Court case, they ask for amicus briefs, they ask for the attorneys to brief the case, they ask questions, there are responses, but you never quite know what they're really going to do with it. That's input. Those are all input.

That's not necessarily involvement in the decision. But if the proposal is that you're deemed to be involved and there hasn't been a passage of time, appropriate amount of time, then you'd be prohibited from applying for grant dollars and that staff would begin to develop and implement

strict policies with firewalls around specific activities and that those with advanced knowledge are prohibited for a defined period, whether that's Methodology Committee members, close relatives, contractors, intra researchers, and we'll get to the table in a minute, that we want to level that playing field and allow qualified individuals to contribute their knowledge and expertise to the development of Patient-Centered Outcomes Research.

And just a reminder, particularly for those people that are listening on the phone, that all the applications and the process, in fact, that we just went through continue to be judged on their merits in a blinded process and that the proposal is that the defined period between announcement and eligibility be the length of one funding cycle and that recusal would be required for the first cycle of the PFAs, and at this point, including priority five, so, the first cycle and that we would also have a wavier policy where somebody could apply for a waiver in a particular situation and that, ultimately, we could change this by appropriate

process and that following approval by the Board, we would put the policy out for comment.

So, now, let me try to walk through this. You have it in front of you if this is not legible. It might well be. It might well be. You got a second document.

So, what we said was that board members would not be eligible, that board members, spouses, domestic partners would not be eligible for the first cycle of the May or the July grants, but they would be eligible for the second cycle of both of those grants. That the Methodology Committee members, board liaisons, so, those are people such as the chair, the vice chair. It was one person from AHRQ, one from NIH, and there may be others who may say for this, I want to be inside, and so, they would sort of go inside the firewall, but once they did that knowingly, they would not be eligible.

That for Methodology Committee members who are not in that position, they wouldn't be eligible for cycle one, but they would be eligible for cycle

two. Same would hold true for Methodology Committee spouses and domestic partners, that interim researchers, medical editors have some advanced knowledge or may have some knowledge. So, again, they would follow that same pattern of not in the first cycle, but they would be able to go to the second cycle.

Deloitte, we've said, would not be eligible at all based on the work that they had done, and then some of the contractors per their agreements, they would not be eligible, that research contractors, because we deem those to be people who were doing input, not involvement, as well as some workshop participants and facilitators. So, that's the table that we put together.

Yes, please?

DR. LEVINE: What's the difference between a research contractor and a PFA contractor?

DR. SELBY: The research contractors worked on the Methodology Report only.

DR. LEVINE: Okay.

DR. SELBY: The PFA contractors worked on the PFAs, and they agreed that they would not be eligible for I think it's like a year. Not life though, Larry, by the way.

MR. BECKER: Ah, okay.

MR. BARNETT: Question. I just want to go for it.

MR. BECKER: Sure, please.

MR. BARNETT: Just the second line down, "board members, spouses, and domestic partners are treated differently than board members."

MR. BECKER: That's the proposal.

MR. BARNETT: Just talk about what's the rationale there.

MR. BECKER: That's where we landed walking through it.

MR. BARNETT: So, they're both excluded for that first cycle, but the notion is that spouses of board members become eligible after that initial period.

MR. BECKER: That's what it says.

MR. BARNETT: That's the proposal.

MR. BECKER: I mean, it's open to this group to have the open debate about do we agree with what's proposed here. There are clearly opinions across the committee and across the Board, as I have spoken to everybody across these categories. So, the purpose here is to put this out in front of us, transparently have the conversation.

CHAIRMAN WASHINGTON: Right, but, Larry, the question is, I mean, having sat through these discussions with the committee, including some outside experts, what was the thinking? I mean, not that you're defending it one way or the other. I mean, I can come up with my own explanation for why that might be the case, but we're interested in hearing what was the committee's thinking. Or whoever favored this in the committee. You don't have to give names. Yes.

MR. BECKER: So, one of the questions we asked was: So, what's an example of where this might be the case? And the case of lawyers came up, husbands and wives are married and are both

lawyers and they work on cases and they don't exchange information about those cases, and so, as Bernie was talking about, there's precedent for that potential.

UNIDENTIFIED SPEAKER: But they're --

CHAIRMAN WASHINGTON: Okay, no, this is on this particular question.

MR. BECKER: Yes.

UNIDENTIFIED SPEAKER: Yes.

CHAIRMAN WASHINGTON: So, we have Sherine and then Ellen and we'll just -- Gail and then Rick.

DR. GABRIEL: And I can just maybe --

CHAIRMAN WASHINGTON: Okay.

MR. BECKER: Okay, go ahead.

DR. GABRIEL: As a member of the committee to reflecting on some of that discussion. I think one of the reasons there are noes almost all the way down the line for the May 2012 cycle is because we didn't have any conflict of interest policies, we haven't had an opportunity to actually enforce anything, and so, the things that Larry talked

about, sunshine, ensuring that information is unidirectional, creating those firewalls, we just hadn't had a chance to do any of that for the May PFA that's released in an hour or whatever.

But I think, and if I may, where I would take issue is I would separate May from July because the July PFA, and this was one of the issues that there isn't entire agreement on, the July PFA, we haven't even put pen to paper on. So, we're in a very good position, I think, to ensure that those firewalls are in place, we're in a good position to make sure that whatever knowledge advantage may exist today has dissipated because certainly, the Methodology Reports, the standards, the contractors' reports will all be out within 10 days. And so, it'll be at least two months for that knowledge of dissipation to occur.

And so, I think we can put in place today conflict of interest policies that say if you're part of the July PFA that, again, we haven't put pen to paper yet, you're going to be in that board liaison category if you're not part of it and you

engage it in discussions that might inform it. Those discussions have to be in the public domain and they have to be unidirectional. So, I think we still have time to put those policies in place for July, but I think the reason you see all those noes for May is because we just hadn't had the time to create and enforce a conflict of interest policy. So --

DR. CLANCY: But just to add one point to that --

CHAIRMAN WASHINGTON: Except for Carolyn asked a different question and we're going to come back to that. If it's on that, we're going to hold that. That's a different question, Sherine. We're going to come back to it. You will definitely have a chance to make your argument for why we want to separate these two. But we have a question on the table now that relates to spouse and/or domestic partner. So, if yours relate to that, please. Carolyn?

DR. CLANCY: So, the point I would agree with Sherine about is we don't have policies in

place. So, taking Larry's example about the Supreme Court, you're right if it's an amicus brief, right? If the principal author of the amicus brief is seen having dinner with one or more Supreme Court Justices; that would call something into question. That would be out of bounds. We have not had that kind of boundaries. In fact, Gene, you wanted the Methodology Committee and the Board to be highly collaborative. So, I don't think it's just about the Methodology Committee Report.

I think the same kind of rationale would apply to spouses, partners, and so forth. We haven't had a policy in place. So, you've got an appearance problem, right? Isn't that interesting? We just funded 20 grants, I'm making up the number here, and 4 of them happen to be people who often have dinner with PCORI board members, blah, blah, blah. How could an applicant who wasn't successful, particularly one who scored pretty well, you're not going to have anything to stand on appeal here, Joe. That's actually the problem.

CHAIRMAN WASHINGTON: Okay, did everybody get the connection here?

I interpret what you're saying is since we have not had a policy in place, it's difficult for us to just retroactively then disqualify. Is that what you're arguing?

DR. CLANCY: No, what I'm saying is I think spouses and partners have to be out for the first round. I think if we put a policy in place, I would be fine with them for future rounds.

I think Joe needs to clarify though are we presuming that these PFAs do not change?

CHAIRMAN WASHINGTON: Okay, but, Carolyn, I mean, this is an important point because I'm trying to understand now spouses and partners are out now.

DR. CLANCY: Yes.

UNIDENTIFIED SPEAKER: For all.

MR. BECKER: In round one.

UNIDENTIFIED SPEAKER: Everybody round one.

CHAIRMAN WASHINGTON: Well, they're out

for cycle one.

DR. CLANCY: Yes.

CHAIRMAN WASHINGTON: The question on the table right now is whether spouses and partners should be out completely. And so, that's why it was a little confusing.

UNIDENTIFIED SPEAKER: Round two.

CHAIRMAN WASHINGTON: So, the question on the table now that's before us is whether or not spouses and partners -- it's not a question. I don't think anybody's debating cycle one, right? I mean, yes --

UNIDENTIFIED SPEAKER: [Off microphone.]

CHAIRMAN WASHINGTON: Right. The question is whether or not spouses and partners are going to be no forevermore, so to speak, certainly for this next year --

DR. CLANCY: So, the question is: Are the PFAs identical?

CHAIRMAN WASHINGTON: Beg your pardon? It doesn't matter. Carolyn, the question for the Board now is it doesn't matter --

DR. CLANCY: But if we have a policy in place that says --

CHAIRMAN WASHINGTON: Yes.

DR. CLANCY: -- board members attest that they don't discuss details of this at home and so forth, then we've got something as a defense, an affirmative defense.

UNIDENTIFIED SPEAKER: [Off microphone.]

CHAIRMAN WASHINGTON: Right, right, but --

DR. CLANCY: Why?

CHAIRMAN WASHINGTON: But now that would be a reason --

DR. CLANCY: Because we don't have a policy in place.

CHAIRMAN WASHINGTON: That would be a reason for if you favor them being in place, but the question on the table, without getting things confusing, is whether or not spouses and domestic partners are going to be allowed to compete? And, Carolyn, if I pick up on where you left, that might be a reason why later on you'd say we have one in place -- but we don't have a policy yet, but we're

talking about what our policy might be right now. So, going back and picking up on -- Sherine, Ellen, Gail, Rick, Harlan, and Carolyn, I'll get you Christine. And then I got you, Leah. Ellen, you're next.

DR. SIGAL: So, on the question of spouses on the Board and in the Methodology Committee, I view it differently, but I will say this, when we were appointed and we had to do our financial disclosure, every piece of stock that we owned or anything that could possibly, whether it was my name or Jerry's name, had to be completely cleansed. There was nothing.

And I can assure you my husband isn't in any industry that has anything to do with what we're doing, but it didn't matter.

MR. BECKER: Right.

DR. SIGAL: We had to be extremely careful and compliant. So, that would beg the question, the spouses for the Board. I mean, now maybe if we do, I think Methodology, if they're not involved and we're going to create PFAs, I frankly think

that we wouldn't have a robust Methodology Committee if everybody would be exempted. At some point, we have to figure this out. The board is a little bit touchier, it's a little bit more complicated. Maybe what Carolyn suggested can work, maybe we can say going forward, here is the protocol, maybe when there's discussion of what we're going to try to do with the PFAs, maybe a spouse or board member whose spouse may apply maybe can be not part of it. I don't know, maybe they wouldn't vote. I don't know, maybe we can do something, but I will say this, I mean, from the financial disclosure point of view, everything that a spouse or partner, I'm sure, had, the GAO considered relevant.

CHAIRMAN WASHINGTON: And can I just pick it up on this point? Let's make sure what we're talking about here is not disclosure. It would be understood that all spouses are going to have to -- and we already do that.

Okay, but in disclosing, I suspect that the GAO looked at that as maybe one of the factors,

but I don't think the GAO will say by definition because you're in a certain area that has the potential for conflict, that you're ineligible, which is what we would be saying with this policy. I just want us to be clear about the difference here. And this is still on the question of spouses.

Gail?

MS. HUNT: Yes, Gail Hunt, Board Member.

CHAIRMAN WASHINGTON: And/or domestic partner.

MS. HUNT: When I read this description of what a conflict of interest is --

MR. BECKER: Where are you?

MS. HUNT: This is the --

MR. BECKER: Yes.

MS. HUNT: -- little paragraph that you've got.

MR. BECKER: Yes.

MS. HUNT: And you've got bolded.

MR. BECKER: I know where you are. I know where you are.

MS. HUNT: You have bolded.

MR. BECKER: Yes.

MS. HUNT: Okay, yes, there you go. Not a lawyer, obviously, but it's pretty clear to me that if anyone, either on the Methodology Committee or on the Board or their spouse or significant other stands to gain $10,000 through fees that they would be getting from their university or whatever, that's a conflict of interest. I'm kind of having trouble seeing how you guys got from this, which I thought was pretty straightforward, to this.

MR. BECKER: So, I actually asked Karl Sleight to read this and give me his opinion. He's the attorney.

MS. HUNT: Okay.

MR. BARNETT: And his view was that it was monies coming from a manufacturer or a pharmaceutical, et cetera. This did not pertain to money coming from PCORI.

MS. HUNT: It's the next sentence that's not bolded. "For purposes of the preceding sentence of financial and benefit includes

honoraria, fees, stock, or other financial benefit." So, goes to a current member or close relative, I thought it was pretty straightforward.

MR. BECKER: Okay.

MR. BARNETT: I think we're talking about two different things. They're related, but they're different. What this statute refers to is what's defined as a conflict of interest. You're absolutely right, it is a conflict of interest, and under the statute, when one of these conflicts occurs, it has to be disclosed and then the Board member would have to recuse him or herself from any decisions that might be implicated. But you can have that conflict, just like there are people sitting around the Board who have similar conflicts and were still put on the Board.

But the issue that we're talking about here is a little bit different in the sense that the statute is silent around the issue of whether or not board members or spouses of board members or anybody else should be eligible for PCORI grants. It goes without saying that there would have to be

disclosure and recusal from the decision-making process, but what's not necessarily clear is whether as a matter of statute they're automatically excluded from being considered for a grant. What Larry and his committee have done is they've said look, we start with the statute, but then we can go beyond the statute as we establish our broader conflict of interest parameters and they've raised this issue of who should be eligible for the grants.

So, your point, I think, is a very good one, that it does make sense to look to this statute kind of as a comparison point, and, clearly, the statute does sweep in together spouses with board members, and, personally --

MS. HUNT: And Methodology Committee.

MR. BARNETT: And Methodology Committee. And, personally, I agree with that because I think that the whole notion is that they're sharing a household, that their financial interest, and to some extent, even the career interests are aligned and one and the same and to me, I think it's

problematic to try to pull apart the Board member from the spouse of the Board member or Methodology Committee member for purposes of determining who should be eligible to apply for a grant and who shouldn't.

MS. HUNT: Yes, and I also think that we need to take into account what the framers of this particular section of PCORI, how they're going to view this. I mean, are they going to say oh, they just sort of weasel worded their way out and said oh, the first round you're okay, but in November, it's okay if a Methodology Committee person or a spouse or a significant other applies. I mean, if they crafted it this way, they may have had very clear intent.

CHAIRMAN WASHINGTON: Okay, Rick. I would also suspect that your committee took into consideration what are the best practices right now.

MR. BECKER: Right.

CHAIRMAN WASHINGTON: And based on what I know in the philanthropic world, obviously at NIH

and AHRQ, this group would not be excluded. This group would have to -- right, Carolyn, in terms of spouses and/or -- I know that's the case for NIH.

DR. GOERTZ: So, at NIH, the spouse of a program officer who wrote an RFA can respond to that RFA? I don't think so.

CHAIRMAN WASHINGTON: No, I'm not talking about a program. We don't write program. We're on the Board.

DR. CLANCY: Right, but the question for AHRQ is not directly on point because we actually don't go to our advisory council with --

CHAIRMAN WASHINGTON: I see. There is no equivalent.

DR. CLANCY: No, it would be a more relevant question for the NIH Research Councils.

CHAIRMAN WASHINGTON: For councils. Yes, so, well, I don't know --

DR. GOERTZ: Well, we're also a governing board, which is really a different role --

CHAIRMAN WASHINGTON: Different, right.

DR. GOERTZ: -- than the National Advisory

Council at NIH. I don't think they're parallel roles.

CHAIRMAN WASHINGTON: I hear what you're saying.

Okay, so, I have Rick and Harlan and then -- okay, well, I mean, I sort of was going down in order here. Actually, I'll hear you next, Joe, and then Bob, but okay. Come on, Rick.

DR. KUNTZ: Rick Kuntz, Member of the Board.

So, I think most people know that I'm one of the conflicts and I think there's another board member or one of the Board liaisons from Methodology Committee has a direct conflict, as well. And I think that to try to make these objective comments as possible in order to contribute to this discussion, the first thing is I guess we assume that we have very healthy communications between spouses. That's the number one assumption. It may not always be true.

[Laughter.]

UNIDENTIFIED SPEAKER: Don't we know that.

DR. KUNTZ: We don't know that there's a free flow of communication. I think what I'm concerned about and just to raise this issue here is that I think it's more than a spouse. Just an example with my wife, she advises post-docs, thesis advisors, and a variety of other junior people who actually look at PCORI as a tremendous resource for them in a large university. I think it would be very difficult to be able to exclude her without excluding the people she mentors because I think that would be in the grants, as well, and I don't know what the level of understanding is with respect to the oversight.

So, the consequences, I think, are to potentially reduce some of the talent that can actually contribute to PCORI to some degree and just something we have to consider. At the end of the day, we have to go with what we think is important with respect to conflicts, but my vote would be to find a solution to manage this and make it transparent because it's just not the spouse alone. I think it would logically have to extend

to people they work with directly.

CHAIRMAN WASHINGTON: Okay, well, Gray wants to respond directly.

DR. NORQUIST: I would just argue I have the same problem. I mean, as a board member, I mentor a lot of people at my university who I cannot now do that and I can make the same argument that how are we going to take care of them? So, I don't know that I'd buy that as the logic that would protect the spouse from not doing. To be honest with you, I think that could apply to all of us.

CHAIRMAN WASHINGTON: Okay, I have Harlan, Carolyn, I have you, but you're down, then Joe and then Leah. Okay, I've got the others, too. Christine.

UNIDENTIFIED SPEAKER: Christine.

UNIDENTIFIED SPEAKER: Christine.

CHAIRMAN WASHINGTON: Okay, I've got Christine.

DR. WEISMAN: My card was raised during the original question that you asked prior to

Carolyn's comment, and I think it's what, Kerry, you began to say, if I understood you right. There's a logical inconsistency in that table. If you put away the whole issue of when we had rules and when we didn't have rules, if the principle is that there's a curing effect on the conflict over time, I get it for the argument on the Methodology Committee. Putting aside what my own feelings are about that, I understand the logic there.

The reason the Board of Governors has governance, we are always conflicted, at least has that potential conflict. There is no way in my mind that time changes the relationship between spouses. I just don't understand it. It's irrelevant. It's either never and we say that there's some way of affidavit, something that we say it's okay, a spouse can do it, but then it's always. It's from day one. Or we say it's never because of the relationship of the spouse with the Board member, but this idea of one funding cycle makes it go away is ridiculous as it relates to a spouse. There is no way.

If the intent was what Carolyn assumed it was, was we had no rules before, now we have rules, so, we're going to put it this one cycle delay and then it goes away forever, I'm okay, but there's no logic to that. All the other ones have a logic that I understand, whether I agree with them or not. This is a logical inconsistency.

CHAIRMAN WASHINGTON: Yes, Sharon had a comment and then I think Joe was next and then Leah. I've got Christine next.

DR. LEVINE: So, I've had my thing up just to say just the opposite, which is that -- Sharon Levine, Board Member. So, I had on the same issue I had just the opposite perspective, which is the amount of time someone has access to knowledge about what PCORI's intent is in terms of the criteria for judging the grants, I think, does have an impact and a leveling factor, but when the grants are submitted and when they're reviewed, they're blinded. And so, the reviewers are looking at grants from individuals who have had presumably a comparable period of time to understand PCORI's

intent and then to respond with a grant application.

When the reviewers review it based on merit and based on impact and based on scientific integrity, they don't know the relationship between the spouse and the Board member. And so, the review is agnostic to the relationship and it seems to me that in itself, the spouse isn't approving the grant, the grants are being brought, and, presumably, if someone's spouse has a grant that has made it through to the point where the Board is approving a panel of grants or a portfolio and there is a spouse of one of the grantees on the Board, perhaps, that individual should recuse them self, but I think up until that point, as long as there has been sufficient time and comparable access to information about PCORI's intent, I don't see why we would want to forever exclude domestic partners and spouses of board members.

DR. WEISMAN: Well, I was just saying what I thought. I just said never exclude them or always exclude them. That was my --

CHAIRMAN WASHINGTON: Okay, we have Joe and rest assured, I'm not calling for a straw vote or any kind of vote today. This is just to clarify this recommendation at this point and to have this kind of discussion to make sure we understand what the issues are and what the options are going to be. And so, with that in mind, Joe and then Leah and Christine.

DR. SELBY: So, a couple of things. I think I actually agree with both Harlan's point and Sharon's point [off microphone].

[Laughter.]

UNIDENTIFIED SPEAKER: That's impossible. Well --

DR. SELBY: They're not in --

UNIDENTIFIED SPEAKER: Hey, Joe, you should --

MS. HUNT: Welcome to my world.

UNIDENTIFIED SPEAKER: Microphone, Joe.

UNIDENTIFIED SPEAKER: Microphone.

DR. SELBY: I apologize. Joe Selby. I'm not on the Board.

And the logical inconsistency is you'd think that spouses would be treated like they're relevant spouses for both, not for one and the other, but I think the ringer here is that board members have sort of said everything else notwithstanding, we will never apply for a grant. I think that's where the illogicality comes in. So, you don't necessarily want to transfer that to the spouse, especially in a standing announcement and I take Carolyn's point that as announcements change, then you have to re-ask yourself that question every time if they do.

Also, it's very important to say this table really applies to this first round of PFAs. After that, I think the filter is what we rely on and not so much this. In other words, if a Methodology Committee member is on the outside vis-à-vis the filter when a new PFA comes out, they don't recuse themselves from the first round. As a matter of fact, oftentimes, the first round will be the only round.

So, this table has to do mostly with these

standing PFAs that are coming out now and we expect them to be up for several cycles, that that's why we talk about cycle two and beyond, and I think the reason that the spouses of board members don't track what the spouses -- the pairings of board members and their spouses and Methodology Committee members and their spouses don't track is simply because board members have just said no matter what, there's no tincture of time for us. There's a tincture of time, by which I mean the advance dissipates over time for everyone else. So, I think illogical, yes, fitting probably also, yes.

CHAIRMAN WASHINGTON: Leah and then Christine and Bob Z.

MS. HOLE-CURRY: Leah Hole-Curry, board member.

One, I appreciate all the work that went into this and setting up the issues that we have to wrestle with here was very well done. So, thank you for the committee's work in this important discussion.

As most of you know, I've been a proponent

that we actually broaden this discussion first and have some baseline ideals that we strive for that we would set this within. However, we also have just things that we need to address and time is of the essence to do so.

I think like a lot of what we've heard today, as a foundational matter, this committee was well set up and I could agree that this compromise as merit. It is a compromise in my opinion and one that I would not personally have chosen, although, I could support it based on the process that was put in place.

I note that there is on this list nothing about PCORI staff. So, I would just ask that that be included. Just I don't need to discuss it here.

But going specifically to the spouses, the issue that I have is I think that this addressed the information potential differential that there would be an advantage based on information that they would be exposed to, but it doesn't address the real or perceived conflict of members that govern this institute awarding significant grants

to a spouse. That's different than the information advantage, which could be managed and by my calculations, it's 40 Americans that would be prohibited potentially if you count centrally the Board and the Methodology Committee, and potentially 40 more if we all have spouses or domestic partners.

So, going to a foundational issue, the risk that we exclude 80 Americans from being funded versus the ideal that members that are intimately involved with this institute would award themselves or their spouses a funding grant is one that I would come down in a different place on.

CHAIRMAN WASHINGTON: Whether you agree or not, I think you'd agree it's quite eloquently stated.

DR. CLANCY: Well, said. Yes.

CHAIRMAN WASHINGTON: Thank you.

Christine?

DR. GOERTZ: Thank you. Christine Goertz, Board Member.

I also want to thank Larry and the team.

I know a tremendous amount of effort has gone into this and I know he's spent a lot of time talking to each of us individually and being very thoughtful through the process.

So, the first thing that I'd like to comment on has to do with the sunlight of time or whatever we'll calling it. I am not convinced that going three months without applying for a grant when you've somehow been involved in the authorship of the PFA actually does level the playing field. I've probably written I don't know how many funding announcements now, probably somewhere around a dozen, and I've actually had the experience of writing a funding announcement for NIH and then six years later, coming in and applying for not the same RFA because that would not be allowed, but a different RFA that actually used some thought processes that were in the original funding announcement that I wrote, and I can tell you it's an advantage. And that was not three months, that was six years, and it just was an advantage.

And so, I think that I can understand why

a lawyer might say that it's not, but because you can talk about how knowledge disseminates over time, but having it on the street for a period of time doesn't replace being involved within the thought process and the strategies when you're putting something together. That is an advantage when we are saying what we mean by "stakeholder involvement" and we're saying what methods are important to us, but if you live and breathe it, that is a different thing than seeing it written by somebody else. I think that it is.

I think that regarding the fact that our spouses that reviewers are blinded to whether an investigator has a spouse on the Board or not, again, I think this is a very small world and many of the reviewers know many of the investigators. In some cases, they may know that this person is the spouse of a board member, in some cases, they may not. I don't know and I don't know how we could even begin to figure that out, but I think there's an appearance of a conflict that's difficult to overcome regardless of what ever sorts

of rules or firewalls. If you're talking about someone being seen having dinner with a Supreme Court justice a couple times, what about having dinner with them every night with your children? It's just something that we need to be thinking of when we're doing this.

CHAIRMAN WASHINGTON: Okay, Bob Z., and then Steve and I'm going to wrap this up Larry [off microphone].

DR. ZWOLAK: Bob Zwolak, board member.

I think that our committee spent a lot of time, substantial amount of time on this exact point, and we were most swayed really by what we felt was the exponentially rapid dissipation of insider knowledge. So, in the creation of the PFAs, assume if the application is due two or three weeks after they're posted on the website, that's one thing, but if they've been up there and all the methodology information, for instance, has been on the website for three or four or five months, it's all available.

And so, that compounded with the fact that

the review is, in fact, agnostic to the marital status or cohort status of the applicant made us feel this was a reasonable approach and, in fact, I'd agree with what Joe said. If there's an inconsistency, it's the fact that the Board members have decided probably appropriately that they would not be applicants.

CHAIRMAN WASHINGTON: Okay. Steve? Are you going to wrap this up?

[Laughter.]

VICE CHAIRMAN LIPSTEIN: Well, I'll try to wrap this up, but I'm certainly stepping outside of my role as Vice Chair, I think. I don't believe that NIH or AHRQ are applicable here because the audience or the public for those respective organizations, while we may think they're the American people, they're largely the research community. And so, if the headline of either the *Times*, *Politico* -- you read *Politico*, right, and if it says Wife of PCORI Vice Chair Receives $2 Million PCORI Grant.

I mean, I could have attested that I

didn't talk to her, I could have recused myself, that may make it into the article in the final paragraph, but the credibility damage to PCORI will be forever. It will be forever and you won't recover from it. It won't be something that you could say we'll change this in the next round.

And so, if we want the national audience to be our audience because of trust, the issue isn't the time, the knowledge, the advantage, the issue is even if I was not in the room, my buddy Gene, my buddy Joe, my buddy Kerry, they all voted for my wife. Even if she was blinded, buried in the grant pool, the perception of impropriety is not surmountable, it's not overcome-able, it's not recoverable. And so, I would encourage us -- and that's very different, by the way, in my mind. If I vote for a grant for Ethan Basch, okay, I don't think I have that same credibility issue. So, I think the Methodology Committee is a different issue from the spouses. But I think the spouses would be a serious, serious threat to our overall integrity.

UNIDENTIFIED SPEAKER: The Board.

VICE CHAIRMAN LIPSTEIN: Of the Board.

CHAIRMAN WASHINGTON: Okay, whether you agree with him or not, just another cogent as well as eloquent statement of a position. And I've heard and many of you have participated in these and other organizations, and I can tell you this discussion is very similar in that it comes down to an issue of perception, real or perceived, and the value that you place on that in terms of the risk compared to whatever benefits will accrue to it, and that's what part of this conversation.

And another is philosophy. I found that in many cases there are individuals along this spectrum that feel that you should deal with any perceived as though they are real and it's no versus those who -- I wouldn't say at the other end, but who feel like let's separate our real versus perceived and find ways to mitigate against perceived. And so, a lot of this, it's sort of somewhere in between, but I sense we're all doing our risk benefit equations as this discussion is

playing out and that this is just on the Board members. We haven't gotten to the Methodology Committee members yet.

And so, we have something at 6:00 and what I would say is that we're going to continue this discussion. We have 14 minutes left literally to wrap this up and get to the Board engagement. And so, at this point, I think we're going to wrap up this discussion, Larry, without going to the question about methodology, but just know that we're going to have that on the table.

I recognize the time factor. Did you comment yet, Christine? I'll get to you then.

DR. GOERTZ: [Off microphone.]

CHAIRMAN WASHINGTON: Okay, so, I thought you did.

I recognize, Joe, the timeline here, and so, to the public, you can expect that sometime, probably by mid-June and probably in the next week, we're going to announce some kind of teleconference or webcast for a public meeting of this board and that we're going to have to move this discussion

along and the expectation is is that we will at that point be continuing this discussion, but have refined this to a point where we will know clearly what the options are and be prepared to vote. So, I see that as the process that we are going to adopt or that I'm proposing we adopt in order to have a decision regarding what our conflict of interest policy will be as of let's say July 1, so to speak, recognizing that these policies are like other policies. We will update them with time and we will update them as we gain experience with this real time.

Okay, so, other comments from Larry or Kerry to wrap this up?

DR. KUNTZ: Real quick comment.

CHAIRMAN WASHINGTON: Okay. Rick?

DR. KUNTZ: Yes, the one comment I'll make on the table is that we talked earlier today about the fact whether priority five could be folded into the November offering in cycle two, and that would make a big difference by those individuals who were held off on the July offering because it would

really mean -- let's take, for example, the Methodology Committee members who might have a proclivity to apply for priority five wouldn't be able to apply until almost a year from now. And if we were to take priority five and put it back into cycle two and get them all lined against, we could do all five together. It would make a big difference, as well, and it's just a comment.

CHAIRMAN WASHINGTON: Well said. Larry, any further comments and I'm going to ask Kerry to wrap this section.

MR. BARNETT: Well, I was just going to ask do we have agreement? And maybe this is opening it up more than you want, but do we have agreement with respect to the first column?

UNIDENTIFIED SPEAKER: The first and the second.

MS. HUNT: First and second.

MR. BARNETT: Yes, and really, the point that I wanted to make is that the PFAs are going out immediately, and so, having clarity around that first column, I think, is very important.

With respect to the second column, we've still got some time, appreciate Rick's comment that some folks may want to have an adjustment there, and then there's a lot of discussion with respect to cycle two, but it seems to me that if there's one thing we can take out of the conversation today is that we're agreed with the committee's recommendation with respect to the first column.

CHAIRMAN WASHINGTON: Okay, while I sense that there is agreement, I think those listening, particularly if you [off microphone] column, you should expect that that column will remain [off microphone]. So, by way of this meeting, we'll putting you on notice, but this is not the official policy.

Anything else, Larry?

MR. BECKER: No.

CHAIRMAN WASHINGTON: Again, I want to say thank you to your committee. Please convey our thanks to all members who are not members of the Board [off microphone] lively and I think spirited and also important and valuable [off microphone].

So, with that, Joe, make any summary comments, and I have a couple before we adjourn for the day.

DR. SELBY: I just want to say thank you to the Board. This was an extremely valuable day, really excellent conversations, lots of help with decisions, and I want to just tell board members and Methodology Committee members and staff members that your next assignment is to be in the steamboat room next-door. Mark says it's just to the left of this room. So, it may be that way.

[Laughter.]

DR. SELBY: But that's at 6:00. So, pretty much just go right on over.

CHAIRMAN WASHINGTON: So, before we conclude, really, I had thought about making a few summary comments, but Ellen just made a statement that captures it all for me and she just said quite a meeting.

[Laughter.]

CHAIRMAN WASHINGTON: Exclamation point. So, on that note, I will also leave the meeting and

announce to the public yet another achievement, and that is that today our annual report becomes available, the first official annual report from PCORI, and for board members and the hundreds of public members here in attendance, there are copies available out at the registration desk, I'm told, and it will certainly be online starting tomorrow. And, again, congratulations to us and importantly thanks to Bill, all the other members of the staff who have been involved in developing not just a report, but helping us to complete the work that's represented in the report.

And so, on that very positive note, I want us to give ourselves a round of applause for this first report.

[Applause.]

CHAIRMAN WASHINGTON: Thanks, everyone.

[Whereupon, at 5:52 PM, the PCORI Board of Governors meeting was concluded.]